



Operating instructions

Small steam sterilizer

STERIDENT STERIMAT STERIMAT_{Plus}



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1 PRODUCT IDENTIFICATION

1.1 TYPE IDENTIFICATION

Small steam sterilizer

STERIDENT, sterilization chamber volume of 15 l;
STERIMAT, sterilization chamber volume of 20 l;
STERIMAT Plus, sterilization chamber volume of 25 l.

These sterilizers are in accordance with
EN 13060
Small steam sterilizers

1.2 NAME AND ADDRESS OF THE PRODUCER

BMT Medical Technology s.r.o.
 Cejl 50
 CZ – 656 60 Brno

2 REQUIREMENTS ON THE USER

- **This product can be operated only by persons, who, on the basis of their appropriate education or knowledge and practical experience, guarantee correct and proper operation. Workers in charge of operating this product shall be trained for this work and made acquaint with these Operating instructions.**
- **The keeper is held responsible for proper training of the personnel in operating the product.**
- Names of the workers in charge of operating the product, further only "user" shall be entered in the so called log of the unit.
- The product shall be operated in accordance with these Operating instructions to secure safety.
- Installation and first putting into operation may be performed only by an *authorized person*¹ in accordance with the instructions specified in chapter 7.4 Installation.
- Pay attention to chapter 8 Operation of the unit before the first use. Incorrect operation may cause damage to the unit.
- The electric installation shall be done by an *authorized person* according to respective regulations¹.

¹ *Authorized person* means a person who, on the basis of his professional education, theoretical and practical knowledge, proved sufficient knowledge in relation to the problematic of steam sterilizers and has a written authorization for servicing the sterilizers STERIDENT / STERIMAT / STERIMAT Plus issued by the manufacturing company.

3 PRESSURE UNITS

For the purposes of this product:

- pressure in **Pa**-units and their multiples (kPa, MPa) means the absolute pressure related to the vacuum (i.e. normal atmospheric pressure is 100 kPa)
- overpressure or underpressure in **bar**-units and their multiples (mbar) means a relative pressure related to the normal atmospheric pressure (i.e. normal atmospheric pressure is 0 bar).

4 PRODUCT SPECIFICATION

4.1 PRODUCT USE

This product (hereinafter referred to as the Sterilizer) is a Class IIa Medical Device and is intended for sterilization of medical devices, i.e. packed, solid, compact, hollow, and porous materials in health care facilities. It enables a quick sterilization of unwrapped instruments destined for immediate use.

The sterilizer is designed for use in medical and stomatological consulting rooms, in hospitals and generally in all branches, where surgical interventions take place.

The sterilizer STERIMAT Plus can be adapted for sterilization of solutions in open bottles, which extends its use to laboratories.

Sterilization is a process, which kills any viable microorganisms inclusive their especially resistant spores. The sterilization inactivates viruses irreversibly.

The sterilization or heating effect on the loaded material is achieved by means of the saturated water steam with the respective overpressure.

4.2 TECHNICAL DESCRIPTION

4.2.1 TECHNICAL FEATURES

- compact dimensions and low weight,
- optimal effective output,
- digital display of temperature in the sterilization chamber,
- digital display of pressure in the sterilization chamber,
- doubled temperature sensors for an independent check of the sterilization process,
- flexible sensor for detecting the temperature in the solution directly, on customer's request (Sterimat Plus only),
- programs with fractional pre-vacuum phase and multiphase drying with the exposure time from 4 to 60 minute,
- possible option of sterilization programs in dependence on the kind of material to be sterilized,
- 3 special test programs,
- time-delayed switching-on and starting the program,
- tempering the sterilization chamber for 1 hour after the program end,
- automatic pre-heating phase keeps the chamber temperature at 80 °C for 1 hour after switching-on the sterilizer.

- sterilization chamber with a heated jacket made of stainless steel DIN 1.4571
- independent pressure-separated steam generator made of stainless steel DIN 1.4571
- automatic door lock
- easy interactive operation by means of the touch-display (graphical LCD)
- Efficient diaphragm vacuum pump connected to a cooler, not requiring connection to a water source
- automatic microprocessor control (two microprocessors master and slave)
- Inbuilt separate storage vessels for supply water and waste water with a filler neck – sufficient for at least 5 sterilization cycles with the maximum possible load
- Indication of maximum and minimum level of supply water and maximum level of waste water
- charge counter
- program input by means of a chip card possible
- interface RS232 for eventual connection to an external printer for program documentation
- connection to an external PC
- communication software "Printer Archiv" for PC under Windows secures storing of programmable data,
- change of program parameters setting by means of the UNICONFIG software possible,
- check of individual sterilization phases during the whole cycle,
- a possibility of connection to the waste water treatment unit at the customer's request,
- a possibility of mounting of the air detector at the customer's request,
- easy and comfortable operation,
- modest maintenance,
- modern ergonomic design,
- easy installation.

4.2.2 PRESSURE VESSEL

The pressure vessel was designed and checked in accordance with the standard EN 13444 Unfired Pressure Vessels and its strength and cyclical stress were tested according to the said standard.

National regulations shall be applied for the operation, service, maintenance, and revisions and tests performance.

4.2.3 DOOR

The sterilization chamber is provided with a door with an automatic electric lock of the chamber. The door is sealed with a special sealing.

4.2.4 WAY OF STEAM SUPPLY

The sterilizer has its own built-in steam generator with a resistance heating body.

4.2.5 CONTROL SYSTEM

An important part of the unit is the double-processor automatics (*master-slave*), that serves for control, regulation and record of the automatic course of operation and evaluates all operating and fault conditions. In case of interrupting the automatic course of operation due to

external influences (electric energy outage) the automatics is able, after restoration of the normal operating conditions, either to continue the operation or to return the sterilizer safely into the initial status.

4.3 TECHNICAL DATA

4.3.1 DIMENSIONS AND WEIGHT

Dimensions of the sterilization chamber

Type of the unit	Dimensions of the useful space (Ø × d) [mm]	Total volume [l]	Useful volume [l]
STERIDENT	238,5 × 310	15	10,5
STERIMAT	238,5 × 430	20	15,5
STERIMAT Plus	269 × 440	25	20

External dimensions of the unit, transport weight:

Type of the unit	External dimensions of the unit (w × h × d) [mm]	Transport weight [kg]
STERIDENT	465 × 425 × 600	82
STERIMAT	465 × 425 × 725	92
STERIMAT Plus	502 × 472 × 750	104

Useful weight

Type of the unit	Weight of the empty sterilizer without water [kg]	Weight with the maximum load and maximum possible water amount [kg]
STERIDENT	56	80
STERIMAT	66	90
STERIMAT Plus	77	102

4.3.2 OPERATING PARAMETERS

Operating overpressure: 0.9 to 2.1 bar (10 to 310 kPa)

Operating temperature: 5 to 138 °C

4.3.3 ELECTRIC ENERGY

Mains connection:.....P/N/PE/AC

Power input:.....2600 W

Operating voltage:.....230 V ± 10 %

Mains frequency:50/60 Hz ± 5 %

Power input in stand-by condition:.....10 W

Overvoltage installation category:.....2

Battery type:.....CR 2430

Fuses:.....6,3 × 32 mm F 16A / 250V 2 pcs

.....6,3 × 32 mm T 1A / 250V 1 pc

4.3.4 EMISSIONS

Average acoustic power: < 65 dB(A)

Radiated heat at the ambient temperature of 25 °C:

Type of the unit	Radiated heat max. [W]
STERIDENT	800
STERIMAT	910
STERIMAT Plus	1020

4.3.5 PROTECTION CLASS

IP 21 – against dropping water.

4.3.6 AMBIENT CONDITIONS AND INTERFACE

Ambient conditions:

ambient temperature:.....+5 to +35 °C
 maximum relative humidity:.....85 % at 31 °C
 maximum altitude:.....2000 m

Serial interface:

type:.....RS 232
 el. isolation.....double

4.3.7 OTHER TECHNICAL DATA

Volume of supply tanks:.....max. 6,5 l / 6,5 l

Information for the continuous checking of the pressure vessel during the operation:

Type of the unit	Supply water consumption [l / cycle]
STERIDENT	0,20 - 1,0
STERIMAT	0,25 - 1,3
STERIMAT Plus	0,35 - 1,7

Max. weight of the load on the dish.....8 kg

Information for the continuous checking of the pressure vessel during the operation:

Type of the unit	Permitted number of the sterilizing cycles
STERIDENT	17700
STERIMAT	17700
STERIMAT Plus	37000

4.4 SAFETY

4.4.1 SAFETY DEVICES

- two-processor check system of the sterilization,
- mechanic – electrical system of blocking the door during the operation,
- system of the door interlocking during the operating cycle by means of the automatic control system,
- Emergency control against door opening in case of imminent hot fluid leakage from the sterilization chamber
- the safety of the pressure vessel is secured, because the sterilization chamber and door are designed and manufactured according to the standard EN 13445 for non-heating pressure vessels
- securing against door opening if the temperature in the sterilization chamber is higher than the boiling temperature of the respective liquid reduced by min. 5 K at the atmospheric pressure outside the unit,
- automatic return to a safe state in case of breaking the program course,
- warning error messages,
- antibacterial filter secures the quality of the chamber aeration after the underpressure drying phase,
- protection against surpassing the maximum operating overpressure by means of safety valves,
- thermal fuse protection against inadmissible overheating of the chamber jacket electric heating,

- thermal fuse protection against inadmissible operation of the steam generator without water.

4.4.2 PERFORMANCE CHECK

4.4.2.1 CHECK BY CHEMICAL PROCESS TEST

- Chemical process tests react by colour change already on the presence of the sterilization media and serve for distinguishing between the goods to be sterilized and the goods already sterilized.
- Every package unit must be provided with this test indicator (it is also possible to use a self adhesive indication tape with the chemical process test, which is stuck on the package containing goods to be sterilized).
- Use only indication tapes destined for steam sterilization.
- This test cannot be used to prove the sterilization efficiency!

4.4.2.2 CONTROL BY MEANS OF CHEMICAL TESTING OF STERILIZATION

- Chemical tests of sterilization react by a colour change if some or all sterilization cycle parameters are achieved.
- Use only chemical tests intended for steam sterilization and the method of test evaluation (colour changes) from its manufacturer.
- This test does not serve as an evidence of sterilization efficiency!

4.4.2.3 CHECK OF STEAM PENETRATION BY MEANS OF THE BOWIE-DICK TEST (BD-TEST)

- We recommend to perform the BD-test regularly every day before the beginning of the sterilization, after having run the vacuum test successfully, if a porous material is to be sterilized.
- The BD-test confirms the correct course of the sterilization program (deaeration, fractional course of vacuum, sterilization temperature during exposure, steam quality...)
- Perform the BD-test by strictly following the instructions of the indicator manufacturer. Only the test device can be placed in the chamber.
- This test device shall meet the requirements of EN 867-5, par. 4.2 and 4.3.

4.4.2.4 CHECK BY MEANS OF THE HOSE TEST WITH CAVITY TYPE A (HELIX-TEST)

- In case this test is required instead of the BD-test, we recommend to perform it regularly every day before the beginning of the sterilization after having run the vacuum test successfully, if a material with cavities is to be sterilized.
- The Helix-test confirms the correct course of the sterilization program (deaeration, fractional course of vacuum, sterilization temperature during exposure, steam quality...)
- Perform the Helix-test by strictly following the instructions of the indicator manufacturer. Only the test device can be placed in the chamber.
- This test device shall meet the requirements of EN 867-5, par. 4.5 and 4.6.

4.4.2.5 CHECK OF THE STERILIZATION CYCLE RECORD

- The sterilizer enables connecting to an external printer and printing a protocol. These protocols serve for documenting the sterilization process quality. An example of the protocols is given in chapter 17.2. The person responsible for the sterilizer operation determines the way of using these documents.

4.4.2.6 BIOLOGICAL CHECK

- Periodical "bacteriological tests with vital spores" give a reliable proof of the sterilizer's functional ability.
- Indicators with *Bacillus stearothermophilus* are used for steam sterilizers.
- When performing biological tests, follow strictly the instructions of the indicator manufacturer.

4.4.3 UNINTENDED USE

Danger of electric shock

- As long as the unit is connected to the mains, it is forbidden to remove or open the covers of the unit. These activities as well as the work on electrical parts may be performed only by an *authorized person* or by a service engineer.

Danger of burns and injury to the operator



- The door of the sterilizer shall not be opened before the end of the sterilization program.



- The material after sterilization is hot. For taking the shelves out, use the withdrawing hook supplied with the sterilizer; for taking other material out, use the gloves!



- **No solutions may be sterilized in the sterilizer STERIDENT / STERIMAT! There is a danger of injury caused by explosion of a bottle when unloading! There is also the danger of damaging the chamber that is not designed for the load that arises when sterilizing solutions.**



- **No solutions in closed bottles may be sterilized in the sterilizer STERIMAT Plus! There is a danger of explosion of a bottle when unloading!**
- **Solutions in open bottles may be sterilized only in the sterilizer STERIMAT Plus and only by means of the appropriate program (additive).**

Danger of damage to the sterilizer

- C as well as the frequency shall correspond.
- No objects, liquids, etc. may be put or located on top of the sterilizer.
- Air vents of the unit shall not be covered up.
- Requirements on the operating media shall comply with the features presented in chapter 12.

- The sterilizer is not designed for sterilization of aggressive solutions that could cause corrosion of the sterilization chamber!

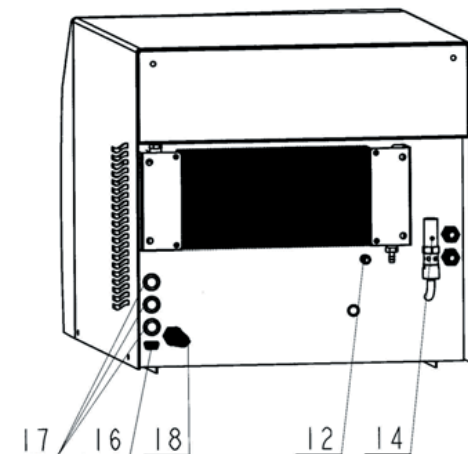
Danger of damage to the load

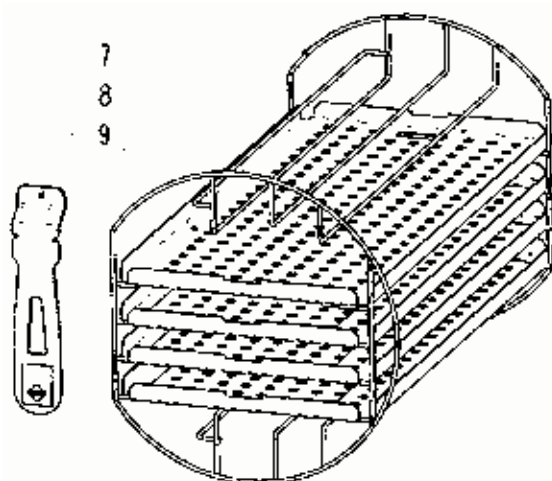
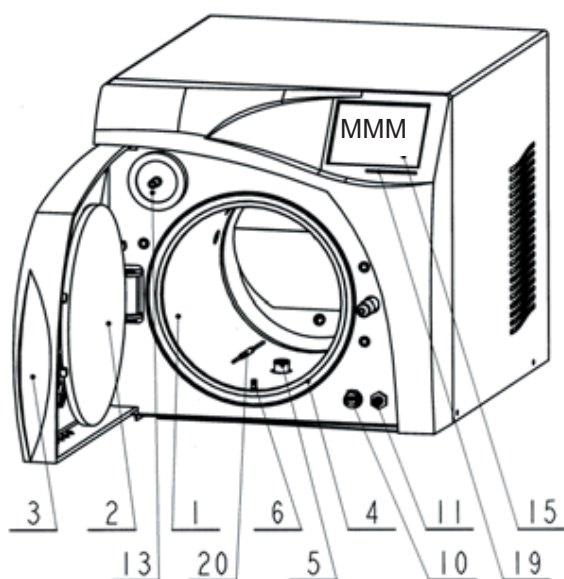
- Organic materials as wool, leather, optic fibers and other thermally unstable items shall not be sterilized with saturated water steam.
- Act upon the data of the material manufacturer or supplier.
- According to chapter 6 select the right program for every kind of load.

5 STERILIZER DESCRIPTION

5.1 INDICATING AND OPERATING ELEMENTS

- | | |
|----|---|
| 1 | Sterilization chamber |
| 2 | Sterilization chamber door |
| 3 | Projection of the chamber door |
| 4 | Door sealing |
| 5 | Drain screen |
| 6 | Pin for built-in piece |
| 7 | Sterilization chamber built-in piece |
| 8 | Unloading holder |
| 9 | Dish |
| 10 | Quick coupler for pumping the supply water |
| 11 | Connector for discharging the used water |
| 12 | Connector for discharging the distilled water |
| 13 | Antibacterial filter |
| 14 | Safety valve of the sterilization chamber and the steam generator |
| 15 | Touch-display |
| 16 | Connector for PC and printer |
| 17 | Fuses |
| 18 | Mains cord |
| 19 | Chip card reader opening (only with the sterilizer STERIMAT Plus) |
| 20 | Flexible temperature sensor (additive only with the sterilizer STERIMAT Plus) |





6 PROGRAMS

The maximum temperature during the whole cycle is equal with the sterilization temperature value increased by 4 K.

6.1 P1 UNWRAPPED QUICKLY 134

Program of a quick sterilization with a single deaeration pre-vacuum for unwrapped massive instruments without cavities at the sterilization temperature and time of 134 °C/4 min. The rapidity of the program depends on the level of preheating the sterilization chamber jacket. Therefore set the sterilizer to the operating mode (par. 8.1.2) and select this program (select and confirm the program) in advance. The chamber jacket will be heated to the temperature corresponding to this program. If you need to keep the sterilizer preheated for more than 1 hour, select the uninterrupted preheating (par. 8.5.12). Use this program for a quick preheating of the sterilizer.

! From the medical point of view this program may be used only in following cases:

- If it is secured (by means of appropriate operating measures), that the sterilized unwrapped material will be used immediately for an invasive operation without being stored or transported. In other cases, when the sterilized material must be protected with a suitable wrapping, this program shall not be used.
- If it is secured (by means of appropriate operating measures), that the sterilized unwrapped material, destined for storing, is considered only as a disinfected material and is used for operations that do not damage the integrity of human body and comes not in contact with injury.

6.2 P2 WRAPPED INSTRUMENTS 134

Sterilization program for porous material (wrapped clothes, wrapped instruments) at the sterilization temperature and time of 134 °C/7 min with subsequent drying.

6.3 P3 TEXTILES, CONTAINERS 134

Sterilization program for porous material (wrapped clothes, wrapped instruments) under special load, e.g. too heavy wrapping (containers, double wrapping) at the sterilization temperature and time of 134 °C/7 min with intensive drying.

6.4 P4 RUBBER, CAVITIES 121

Sterilization program for wrapped, thermally sensitive materials e.g. made of rubber or steam resisting plastics, for hollow bodies and hoses at the sterilization temperature and time of 121 °C/20 min with subsequent drying.

6.5 P5 WRAPPED QUICKLY 134

The program designed especially for the load weight of max. 0.5 kg for the sterilization of porous material (wrapped clothes, wrapped instruments) at the sterilization temperature and time of 134 °C/7 min with subsequent drying.

The rapidity of the program depends on the level of preheating the sterilization chamber jacket. Therefore set the sterilizer to the operating mode (par. 8.1.2) and select this program (select and confirm the program) in advance. The chamber jacket will be heated to the temperature corresponding to this program. If you need to keep the sterilizer preheated for more than 1 hour, select the uninterrupted preheating (par. 8.5.12).

6.6 P6 CAVITIES QUICKLY 121

The program designed especially for the load weight of max. 0.5 kg for the sterilization of wrapped, thermally sensitive materials e.g. of rubber or steam resisting plastics, for hollow bodies and hoses at the sterilization temperature and time of 121 °C/20 min with subsequent drying.

The rapidity of the program depends on the level of preheating the sterilization chamber jacket. Therefore set the sterilizer to the operating mode (par. 8.1.2) and select this program (select and confirm the program) in advance.

The chamber jacket will be heated to the temperature corresponding to this program. If you need to keep the sterilizer preheated for more than 1 hour, select the uninterrupted preheating (par. 8.5.12).

6.7 P7 SPECIAL

Specific programme modified upon the customer's wishes. In STERIMAT Plus, the programme can be modified by means of a chip card. The programme data of the special programme remain permanently in the unit memory unless they are overwritten by other data. Chip card handling is described in Articles 8.6.16 and 8.6.17.

Often required customer programs:

Turbines, extension pieces – 134 °C / 7 min + drying, for porous and hollow items.

Prion – 134 °C / 60 min + drying, for porous and hollow items.

Disinfection – 105 °C / 20 min + drying.

Use this program for loads only in a preheated sterilizer (sterilization chamber temperature at least 50 °C).

The program **Solutions** - additive only with the sterilizer STERIMAT Plus is an example of the special program. This program requires the use of a flexible temperature sensor. The sterilization cycle parameters (evacuation, sterilization temperature, sterilization exposure time) can be modified according to the customer's wishes. As a standard, the time of the sterilization exposure is 30 min and the sterilization temperature is 121 °C, the air evacuation is performed in the gravitational way and there is a spontaneous cooling-down after the sterilization end.

6.8 P8 BOWIE & DICK TEST 134

The program is a test of steam penetration into porous material. It is performed at 134 °C/3,5 min. The test is used to ascertain whether the deaeration of the test porous space and the subsequent steaming is sufficient and whether the required temperature is obtained in the space during the whole period of sterilization exposure. For the BD-test we recommend to use single test packs or special metal frames for repeated use. The test sheet shall show a uniform colour after the test. Light spots on the test sheet testify to an insufficient penetration of the steam. When using the BD-tests (packs, metal frames) follow instructions of their manufacturers.

Note: The BD-test is not considered to be a sterility test!

6.9 P9 HELIX TEST 134

The program is a test of steam penetration into hollow material. It is performed at 134 °C/3,5 min. The test is used to ascertain whether the deaeration and the subsequent steaming of the test cavity is sufficient and whether the required temperature is obtained there during the whole period of sterilization exposure. For Helix test a special hose with chamber for inserting a chemical indicating strip is used.

The indicator strip should show a uniform colour after the test. Light spots on the indicator strip testify to an insufficient penetration of the steam.

When using the Helix tests follow instructions of their manufacturers.

Note: The Helix test is not considered to be a sterility test!

6.10 P10 VAKUUM TEST

Air removal from the sterilization chamber, especially from the goods to be sterilized, and keeping the sterilization chamber vacuum-tight is the basic precondition of a successful sterilization, securing that all germs will be killed. Otherwise the remaining air (or the air streaming into the chamber due to the untightness) would create "air nests" inside the porous material and with regard to poor thermal conductivity of the air it would not be possible to reach the necessary sterilization temperature in the said nests. Therefore the program control is provided with a vacuum test (VT) to prove tightness of the sterilizer chamber under vacuum.

The vacuum test is performed as follows: the chamber is evacuated, a 5 min. equalizing phase follows and then comes the actual test, lasting 10 minutes.

For a successful performance of the vacuum test the temperature inside the chamber must be equal with the ambient temperature $\pm 5^\circ\text{C}$.

*** Note:** The values of the program courses are represented in chapter 17.3.

6.11 P11 SERVICE

This program enables to enter the service mode.

6.12 CYCLE LENGTHS

STERIDENT

Program	Cycle duration without load* after warming-up [min]	Cycle duration max. load after warming-up [min]	Notes
P1 Unwrapped instruments 134	18	35	From the cold state the duration is longer by 15 min.
P2 Wrapped instruments 134	40	65	
P3 Textiles, containers 134	50	75	
P4 Rubber, cavities 121	70	100	
P5 Wrapped quickly 134	30	40	Max. load 0,5 kg
P6 Cavities quickly 121	55	65	Max. load 0,5 kg
P7 Special			
P8 Bowie & Dick test 134	20	Not performed;	With test device inserted;
P9 Helix test 134	25	Not performed;	With test device inserted;
P10 Vacuum test	20	Not performed;	Performed in cold condition;

*Without dishes.

STERIMAT

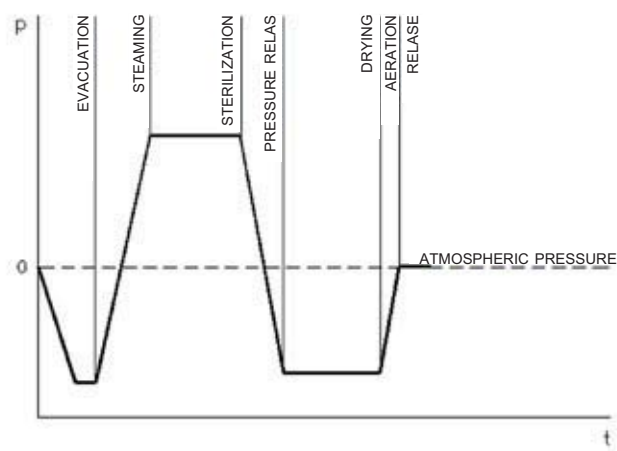
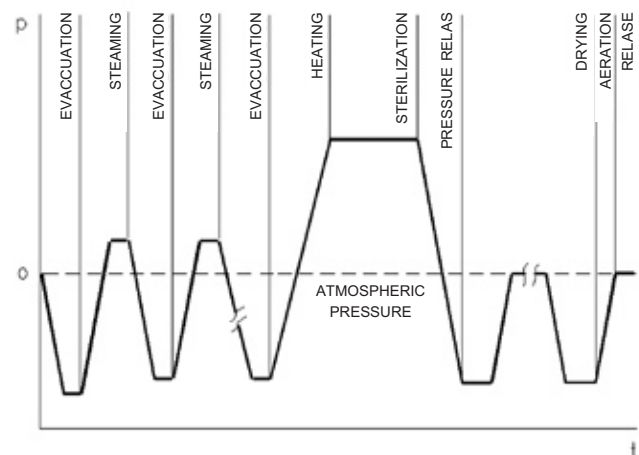
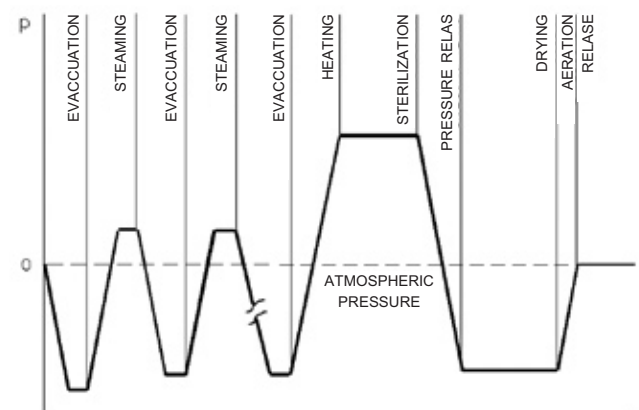
Program	Cycle duration without load* after warming-up [min]	Cycle duration max. load after warming-up [min]	Notes
P1 Unwrapped instruments 134	25	45	From the cold state the duration is longer by 18 min.
P2 Wrapped instruments 134	60	95	
P3 Textiles, containers 134	75	115	
P4 Rubber, cavities 121	85	120	
P5 Wrapped quickly 134	40	50	Max. load 0,5 kg
P6 Cavities quickly 121	72	90	Max. load 0,5 kg
P7 Special			
P8 Bowie & Dick test 134	23	Not performed;	With test device inserted;
P9 Helix test 134	50	Not performed;	With test device inserted;
P10 Vacuum test	23	Not performed;	Performed in cold condition;

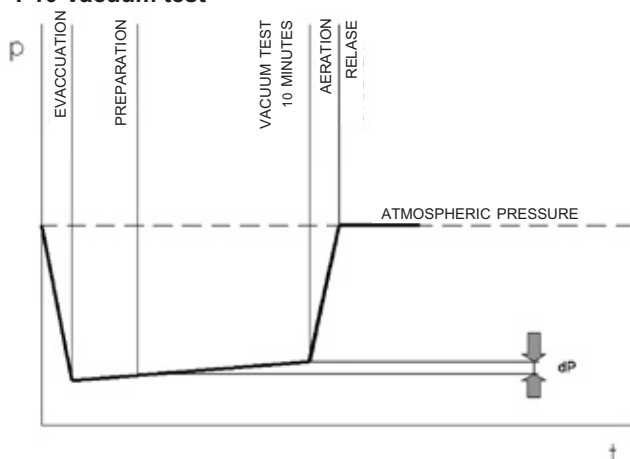
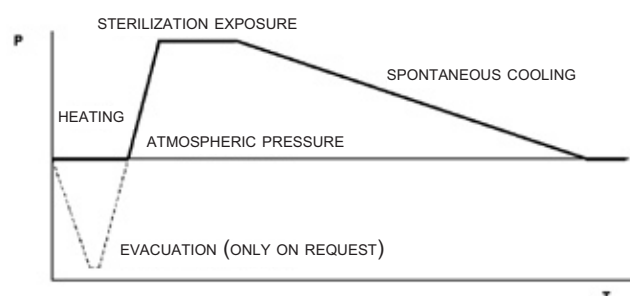
*Without dishes.

STERIMAT Plus

Program	Doba trvání cyklu bez vsázky* rozeřtý stav [min]	Doba trvání cyklu max. vsázka rozeřtý stav [min]	Poznámky
P1 Unwrapped quickly 134	30	50	From the cold state the duration is longer by 20 min.;
P2 Wrapped instruments 134	75	110	
P3 Textiles, containers 134	95	130	
P4 Rubber, cavities 121	110	160	
P5 Wrapped quickly	50	55	Max. load 0,5 kg.
P6 Cavities quickly 121	80	100	Max. load 0,5 kg.
P7			
P8 Bowie & Dick test 134	25	Not performed;	With the test device loaded;;
P9 Helix test 134	55	Not performed;	With the test device loaded;
P10 Vacuum test	25	Not performed;	

*Without dishes.

6.13 COURSES OF OPERATING CYCLES**P1 Unwrapped quickly 134****P2 Wrapped instruments****P4 Rubber, cavities 121****P6 Cavities quickly****P3 Textiles, containers 134****P5 Wrapped quickly****P8 Bowie & Dick test 134****P9 Helix test 134**

P10 Vacuum test**P7 Solutions**

7 PREPARATION OF THE STERILIZER FOR USE

7.1 TRANSPORT AND STORAGE OF A NEW STERILIZER

After the transport keep the sterilizer in the original transport packing from manufacturer. Avoid impacts of the packed sterilizer against walls and other barriers. Till the time of unpacking store the sterilizer at a dry covered place with the ambient temperature of min. 5 °C.

7.2 UNPACKING THE NEW STERILIZER

For unpacking the sterilizer the tools used in a common household are sufficient. Keep the packing for an eventual transport to another workplace or for storing. Keep the packing, anyway, during the whole warranty period, so that you can send the sterilizer for an eventual reclamation.

7.3 SAFE DISPOSAL OF THE PACKING

For the disposal of the packing material proceed as described in chapter 14.1.

7.4 INSTALLATION

The sterilizer is carried in vertical position by catching it by the bottom edges on the sides of the device. The first putting into operation may be performed only by an *authorized person*. It is necessary to perform the automatic watering according to par. 8.6.13 and the storing of calibrations, so that from the sterilizer installation date the time for the message “Service inspection” starts to be counted. The sterilizer shall be placed on a hard leakproof horizontal floor, on a stable desk or another stable base.

Caution:

Sterilizer is a device in which water steam is generated and then condensed, which is connected with the necessity to provide for pressure equalization in the sterilization chamber and the sterilizer waste vessel with the ambient atmospheric pressure. It is therefore natural that some both gaseous and fluid humidity gets to the sterilizer surroundings after the door opening at termination of an interrupted programme, or in case of use of a programme with a short period of drying, and from overflow hoses on the back side of sterilizer in case of intense use or defect. Therefore, no equipment which is not waterproof may be placed under the sterilizer.

The rear edge of the upper and side cover must be placed minimally 10 cm from the wall because of the air flow coming out of the sterilizer.

Minimum distance of the unit's side walls from the walls is 30 mm (with respect to a sufficient access of cooling air and an increased width of the device when opening the door). Minimum distance of the unit's upper side from the wall is 150 mm (because of cleaning the drain tank).

Caution:

The minimum load capacity of a table for sterilizer placement must be 125 kg.

An electric socket must be available within the reach of the sterilizer supply cable.

To start the sterilizer, prepare approx. 7 litres of supply water (distilled water is recommended) in a can.

Work media requirements – see Chapter 12.

7.5 ARRANGEMENTS BEFORE THE USE

There is the original technical documentation and the sterilizer equipment placed in the sterilization chamber and wrapped in a plastic cover. Do not forget to remove these items immediately after placing the sterilizer on its working place. When opening the sterilization chamber proceed according to par 8.1.1, 8.1.2 and 8.1.3.

8 OPERATING THE STERILIZER

The description of chapter 5.1 Indicating and operating elements is used in this chapter.

8.1 BASIC OPERATION

8.1.1 TOUCH-DISPLAY

The touch display 15 serves for communication and control of the sterilizer. All necessary information is shown on the display. The required function is selected by finger touch on the field represented as a button. The display reacts on a slight touch, it is not dimensioned for a high press.



- You could cause a damage to the display by pressing it too much!

8.1.2 STAND-BY MODE AND OPERATING MODE

After connecting the mains cord 18 to the el. socket the sterilizer is in the so called **stand-by mode** – the sterilizer does not perform any function, the consumption of el. energy is insignificant. If the sterilizer does not start to operate within 5 minutes, the illumination of the touch-display 15 goes off. The illumination goes on after touching the display 15 at any place. The touch-display 15 is active and after touching the display 15 at any place the sterilizer gets to the **operating mode**.

In the operating mode you can select a program, start the program and break the program, perform service operations accessible to the operator, open and close the door. The field "Switch off" serves for transition from the operating mode to the stand-by mode.

8.1.3 STERILIZATION CHAMBER DOOR

The door 2 is unblocked after touching the corresponding field on the display 15. The projection 3 enables to catch the door with fingers and open it.

Check the proper fixing of the sealing 4 – the sealing 4 must not be pulled out of its groove; the automatic control would evaluate that as insufficiently closed door 2. When closing the door 2 them ajar at first and then press the door 2 for min. 4 sec so that it can be closed and secured automatically.

If the sterilizer is in the stand-by mode, we recommend to leave the door 2 ajar so that the sealing 4 is not bruised unnecessarily.

8.1.4 MANIPULATING THE GOODS

To take hot dishes 9 out of the sterilizer, use the dishes holder 8 which belongs to the standard sterilizer equipment. The dishes 9 are slid in the built-in piece 7 of the sterilization chamber. The built-in piece 7 can be removed from the sterilization chamber 1 and cleaned. When putting the built-in piece 7 into the sterilization chamber 1, don't forget to slide the built-in piece 7 on the special pin 6. Those possibilities of the sterilization chamber space use are shown in Article 11.3.



Warning:

After the end of the program the inner surface of the door 2 and the chamber jacket 1 are hot, be careful when

unloading the sterilized goods, danger of burns! Use the unloading holder or gloves!

8.1.5 SUPPLY WATER

The sterilizer needs supply water to generate steam. When drawing water to the inner reservoir of the sterilizer, proceed as follows:

- Push the drawing hose connector (part of standard equipment) into the quick coupling 10 for the supply water drawing. This quick coupling is marked with the symbol „IN“.
- Put the free end of the hose in the vessel with the supply water. The recommended quantity is 7 L.
- Start the drawing process by touching the field "Fill in water" on display 15. Drawing can be started at any time if the door 2 is open; the sterilizer will not be overfilled.
- After the drawing is terminated, release the hose connector by pressing the button on the quick coupling 10.
- Water quality data – see Article 12.1.

Warning:

Pay attention to proper immersion of the end of the hose to water. Never start "dry" drawing. Drawing without water breaks the pump.

Caution

Use of supply water of worse parameters than those stated here can reduce the service life of the device or reduce markedly the parameters guaranteed by the manufacturer. It can be the reason for the manufacturer to cancel his guarantee.

8.1.6 DISCHARGE OF THE WASTE WATER

Due to the sterilizer functioning, waste water accumulates inside the sterilizer. The waste water must be discharged in the following way:

- Insert the free end of the discharge hose (part of the standard equipment) in the waste vessel.
- Slide the quick coupling of the discharge hose on the waste water discharge connector 11. This connector is marked with a symbol "OUT". The waste water starts flowing away immediately. The maximum amount of water is 7 L. The waste water may be discharged at any time if the door 2 is open.

8.2 PREPARATION OF THE LOAD TO BE STERILIZED

When saturated water steam enters the chamber, condensation of the steam on the loaded goods takes place. Yet, a residual air and other non-condensable gases restrain an ideal transfer of thermal energy from the steam onto the goods being sterilized.

Removal of the mentioned gases and securing satisfactory drying of the sterilized load are very important. The sterilized material plays an important role in this case.

Decisive parameters co-acting during sterilization:

- Quantity of heat supplied into the sterilized load, i.e. the temperature rise, weight and specific heat of the loaded material.

- Flow resistance, i.e. the factor influencing the speed of air removal from the sterilizer load.
- Uneven distribution of moisture due to condensate dropping down during sterilization of instruments.

8.2.1 TEXTILES

Folded textiles consume a large quantity of thermal energy when being heated. Due to their large airflow resistance folded textiles hold back air. Therefore textile loads shall be sterilized only at fractional course of vacuum. Textile pieces shall not be compressed each other, also their location in the sterilization container should be loose. The specific mass of normally wrapped textiles is approximately 0.11 kg/dm³. Recommended textile load is 2 kg. Maximum mass of textile for one load is 2.5 kg.

8.2.2 INSTRUMENTS

When heating heavy instruments a large quantity of condensate arises on their surface, which is dropping down and humidifies the other goods being located in the lower part of the sterilization chamber. Therefore it is advantageous to locate heavy instruments on the lower dish or tray. The quantity of condensate is substantially dependent on the character and weight of the instrument itself.

Articulate instruments shall be opened or disassembled before loading them into the chamber, which makes the removal of residual air and condensate from hardly accessible parts easier. Mutually connected instruments or their parts create narrow gaps, which are quickly filled with condensate during steam sterilization. The thermal energy, accumulated in the instrument, is transferred also to the condensate collected in the said gaps, that is heated up to the sterilization temperature as well. But in comparison with direct heating by condensing saturated water steam this process requires much more time.

Before the sterilization the material shall be cleaned and dried in an appropriate way.

The recommended load of metal material is 7.5 kg.

Maximum mass of metal material for one load is 10 kg.

8.2.3 RUBBER GOODS

Rubber is sealing material in principle. The sterility of rubber parts can be achieved on condition that individual surfaces remain separated from each other. Rubber aprons or scarves can be sterilized with the aid of thicker textile pieces inserted between the surfaces or rubber material; here textiles assist in penetration of steam.

To avoid damage to rubber by heat, sterilization is performed at the lower temperature of 121 °C and with longer sterilization exposure time. Having finished the sterilization cycle, it is necessary to remove the rubber load from the hot sterilization chamber as soon as possible.

8.2.4 SPECIAL MATERIAL

A large quantity of condensate arises in **thick-wall hoses**. In case the hoses are not laying horizontally, the condensate is collected in the lowest part of the hose. Deaeration of deep cavities in catheters and in some instruments is

very difficult. A lot of residual air and condensate remain between flat parts of the instruments if there is a narrow gap between them during sterilization. Such parts and hollow bodies shall be also sterilized with fractional vacuum pre-cycles with a sufficiently long sterilization exposure.

In case of **dishes** loaded with goods and stacked one over the other in the chamber it is necessary to secure sufficient removal of residual air, and thus making penetration of steam easier, by insertion of sufficiently thick textile layers between the individual dishes. Due to condensation of steam it would be very difficult to separate the trays stacked without using textile pads after sterilization. Objects of dish or spoon shape should be turned with their mouth down.

Vessels with covers or other containers without open outlets can get deformed due to the alternation of steam pressure and vacuum, or they can be non-sterile. Such objects are not suitable for steam sterilization.

Empty bottles are recommended to be sterilized with their bottoms up using the program with 121 °C. Otherwise the condensate accumulated during sterilization at the bottom of the empty bottle cools down very quickly during the drying in vacuum. Consequently a heavy heat stress arises in the glass, which could cause bursting of the bottle bottom. Never put the bottles by their large surface on a metal support.

Silicone prostheses, as well as some **endoscopes**, may be sterilized in saturated water steam. Follow the instructions of their producer.

8.2.5 SOLUTIONS

In case of the special program **Solutions** insert the flexible sensor into the vessel (so called reference bottle) with the solution whose temperature is at most the same as the temperature of other solutions in vessels sterilized together, so that it is at least by 20 mm submerged in the sterilized medium. The sterilization exposure itself is started after reaching the sterilization temperature in the bottle. If the flexible sensor is not submerged in the solution properly, it will sense only the temperature of the sterilization medium and the temperature changes in the solution will be delayed behind the values on the sensor, the sterilization will be insufficient and during the cooling phase after the sterilization exposure the solution temperature will be higher than the temperature on the sensor. The temperature in the reference bottle shall not be higher than the temperature in the load (e.g. exchanging the reference bottle or its content after each sterilization). The reference bottle is a bottle with the same volume and the same solution as the bottles to be sterilized. The reference bottle is not supplied with the sterilizer.

In case of sterilization in small bottles it is possible to use a bottle of a suitable larger volume as a reference bottle so that the temperature sensor can be inserted. The reference bottle shall be placed in the bottom part of the sterilization chamber (theoretically the coolest part).

It is recommended to fill the bottles to be sterilized only up to two thirds of their volume, so that their content does not boil over out of the vessel. In case of a program with evacuation the temperature of the load shall be max. 25 °C and the sterilization cycle shall be started immediately after loading

the sterilization chamber in order to avoid the undesirable overheating and subsequent boil of the medium being sterilized during the evacuation.
The maximum amount of solution for one load is 6 l.

Caution:

When sterilizing solutions the flexible sensor shall be submerged in the reference bottle for the reasons of a perfect sterilization and for keeping the safety regulations when unloading the bottles with the solution.

8.2.6 WRAPPING MATERIALS

Materials destined for wrapping of goods to be sterilized shall comply with the requirements of the standards EN 868-1 to 5 and EN 868-8.

Following materials are considered:

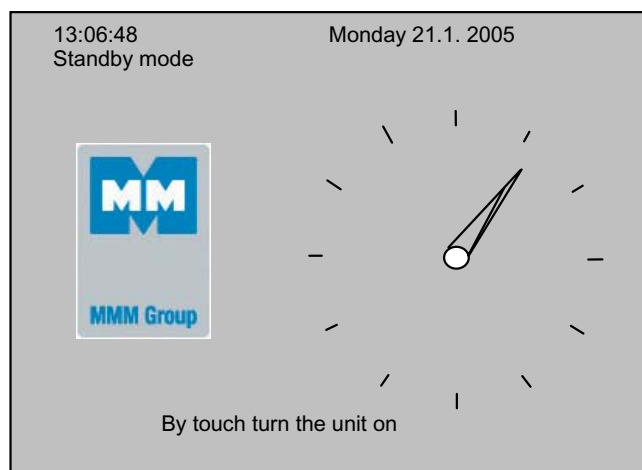
- plain paper
- crêpe paper
- fabric
- non-woven wrapping material
- thermally sealable and self-adhesive transparent bags and rolls of laminated foils paper-plastics
- containers with repeatable use.

8.3 DAILY PUTTING INTO OPERATION

Initial state:

- Mains cord **18** is connected to the el. socket;
- Door **2** open;
- Stand-by mode;

The display **15** shows:



8.3.1 CHANGING TO THE OPERATING MODE

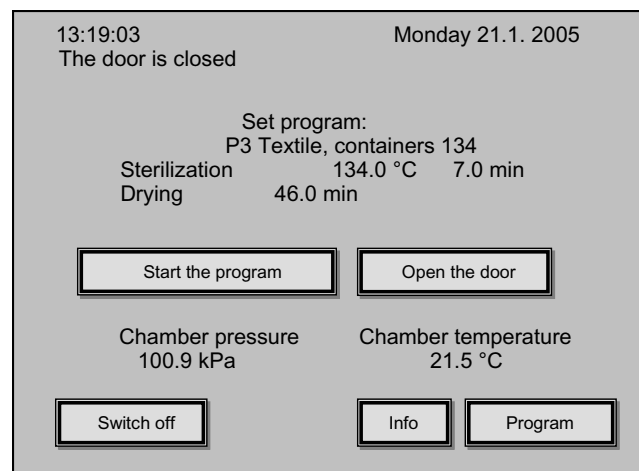
Touch the display **15** at any place.

8.3.2 PREPARATION FOR STARTING THE CYCLE

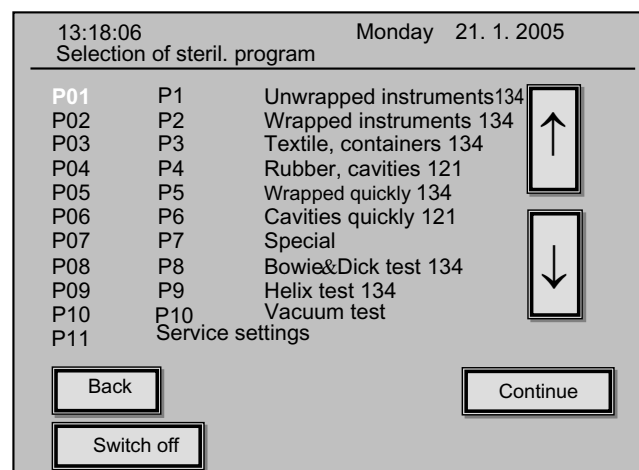
Load the goods to be sterilized into the chamber **1** according to chapter 8.2.

8.3.3 STARTING THE CYCLE

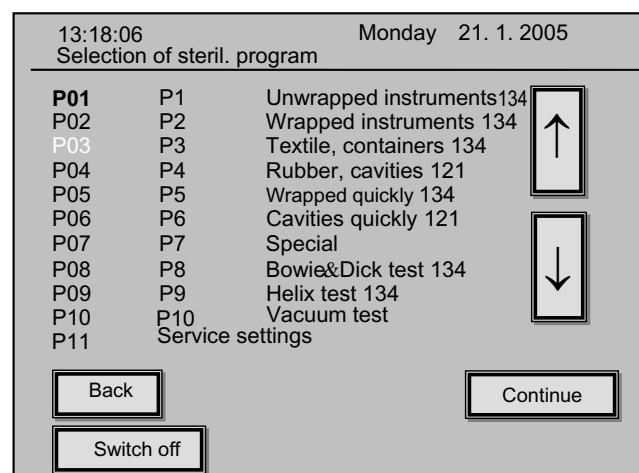
- Close the door **2** (par. 8.1.3), the display **15** shows:



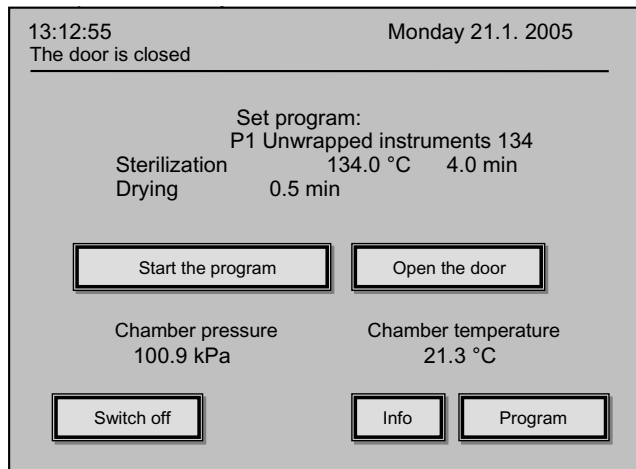
- After touching the field "Program" the display **15** shows:



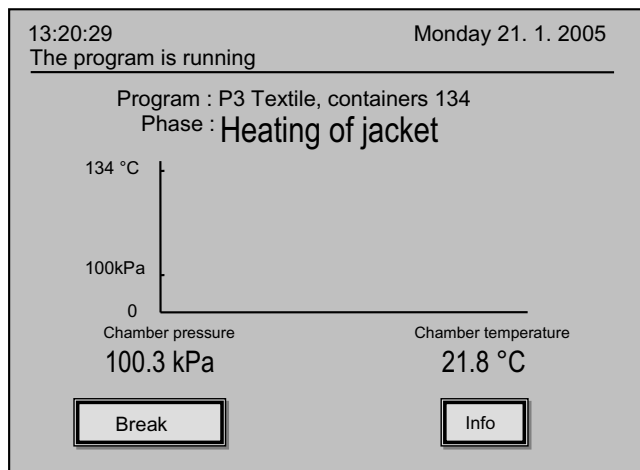
- Mark the required program by means of arrows.



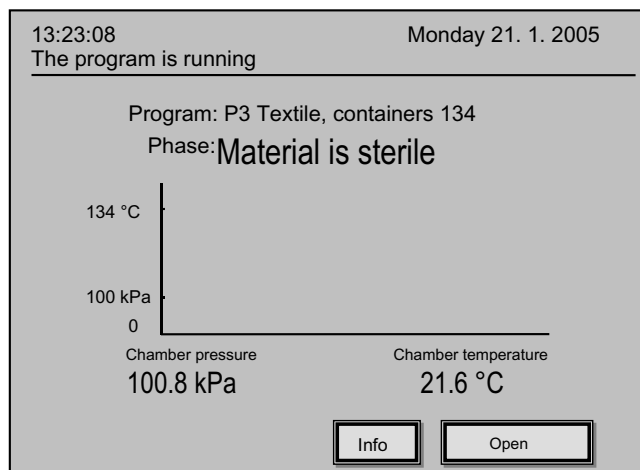
- Confirm the marking by touching the field "Confirm".
Following data are shown:



- Start the selected program by touching the field „Program start“. Data on the running program are shown on the display.



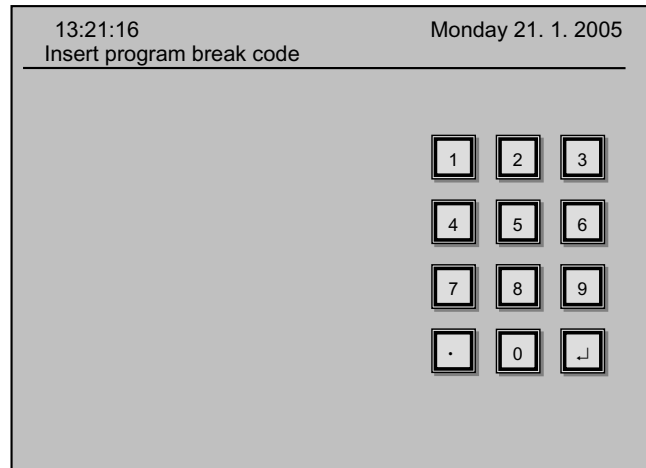
- After termination of the programme, information about its accomplishment is displayed. By touching the right or left side of the displayed graph, you can move the graph.



8.4 PROGRAM BREAK

If it is necessary to break the program for any reason, it could be done any time during the whole sterilization cycle. The break is protected by a code and is carried out in following way:

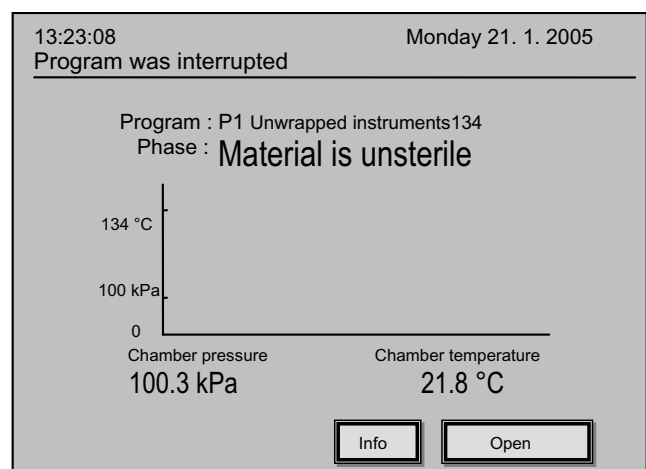
- Touch the field "Break" to activate it. The display **15** shows:



- Enter the number code by means of the numerical keyboard. In case the code entering is not started within ca. 10 sec, the menu is canceled automatically. There is a **code: 0** preset in the sterilizer. After entering the right code confirm it by touching the field ↵. The program is broken. Further operation is performed automatically.
- The code can be changed in the service program according to par. 8.6.6.

If the program is in the phase before filling the sterilization chamber with steam, the chamber pressure is equalized with the atmospheric pressure.

If the program is in the phase after filling the sterilization chamber with steam, a short drying is carried out and the chamber pressure is equalized with the atmospheric pressure. After the end of the interruption the display **18** shows:



Then the door **2** can be opened and the chamber **1** unloaded.

Warning:

In this case the load cannot be considered sterile.

Caution:

A new cycle cannot be performed with the wet load from the broken cycle.

8.5 CONNECTION TO PC AND PRINTER

A PC or a printer can be connected to the sterilizer, by means of which

- protocol
- protocol with graphical record of pressure and temperature course
- protocol with digital record of pressure and temperature course can be printed.

The printer has its own Operating instructions, which shall be studied properly before using the device.

The connector **16** for connecting the PC or printer is placed in the rear wall of the sterilizer.

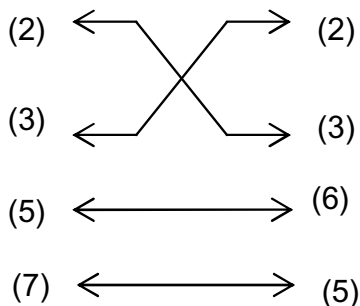
Select the type of printing by means of the program **P11 Service** according to par. 8.6.8.

Some printout samples see chapter 17.2.

The sterilizer supports the print to Megatron DPT-6333 printer in a Printer Archives or Procedures Documentation programmes. The communication interface RS232 of 9600Bd, 8 bits, no parity, and flow control RTS/CTS is used for all cases.

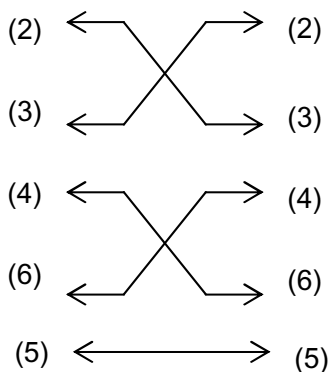
Connection of the print cable to the printer:

Canon-25M x Canon-9F



Connection of the print cable to PC:

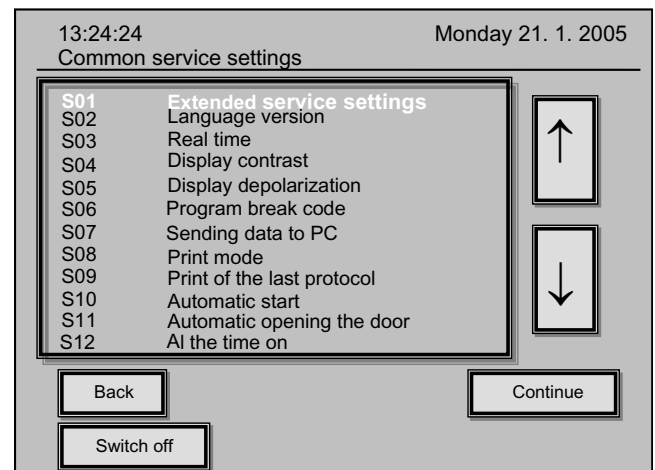
Canon-9F x Canon-9F



8.6 FUNCTION, SERVICES AND SETTING THE PROGRAM P11 SERVICE

To understand the communication with the sterilizer by means of the touch-display **15** study the sterilizer operating described in chapters 8.1 and 8.3.

After selecting the program **P11 Service** (the same procedure as in par. 8.3.3) following data are shown on the display **15**:



By means of the arrows select the appropriate service function, service or setting. Confirm the selection by touching the field "Confirm".

8.6.1 EXTENDED SERVICE SETTINGS

These service settings can be activated only by an authorized person.

8.6.2 LANGUAGE VERSION

This service serves for selecting the language for communication with the sterilizer. After selection and confirmation "Language version" the screen with language menu is displayed. Mark the selected language by means of the arrows and confirm by touching the field "Confirm". The language is changed immediately. End of the program and return to the basic program **P11 Service** are performed by touching the field "Back".

8.6.3 DATE AND TIME

This service enables to set the actual time and date. After selection and confirmation "Date and time" the data on date and time together with numerical keyboard are shown on the display. Touch the number you wish to change, the number becomes active, and then enter a new number by means of the keyboard, then confirm the selection by touching ↵. End of the program and return to the basic program **P11 Service** are performed by touching the field "Back".

8.6.4 DISPLAY CONTRAST

This service enables to set the contrast of the touch-display. After selection and confirmation "Display contrast" the

contrast shown in percents can be changed by means of the arrows. Store the set contrast by means of the field "Confirm". Then the return to the basic program **P11 Service** follows automatically. If the contrast is not changed or the setting confirmed within 5 sec, the contrast will be set to the initial value and the return to the basic program **P11 Service** is performed.

The display contrast can also be changed without selecting the function "Display contrast", i.e. with any display. If you wish to increase the contrast, touch two places at the same time – the upper right corner and the middle part under the upper display side. If you wish to reduce the contrast, touch the upper left corner and the middle part under the upper display side.

8.6.5 DISPLAY DEPOLARIZATION

This service enables to "clean" the display of undesirable images. After the activation of this service the data on the display are erased and then shown on the display again. The menu of the basic program **P11 Service** is shown at the same time.

8.6.6 BREAK CODE

This service enables to change the code that is required for program breaking. The code is entered by means of the numerical keyboard and confirmed with the field ↵. Return to the basic program **P11 Service** is performed at the same time. A 1- to 6-digit-code can be entered.

8.6.7 RECORDING THE DATA TO PC

At present the data recording to PC is being prepared.

8.6.8 PRINTING MODE

This service enables to select the required form of the document (protocol) printed with the connected printer or the program PrinterArchiv, which is an independent product. The time interval of printing the record of the pressure and temperature course is 10 sec. Various forms of the printout are shown in chapter 8.5.

After confirming this service a menu is displayed, by means of which, after selecting and confirming, following functions can be selected:

„Automatic protocol printing“ – a protocol is printed automatically after the program end with the following preset directives. For printing from the service mode see par. 8.6.9;
 "Print graph" – printout of protocol with graphical record of pressure and temperature course;
 "Print values" - printout of protocol with digital record of pressure and temperature course;
 Return to the menu of the program **P11 Service** is performed by touching the field "Back".

8.6.9 PRINTING THE LATEST PROTOCOL

This service enables an additional printout of the latest program protocol, where the selections "Print graph" and "Print values" are used, see par. 8.6.8.

8.6.10 AUTOMATIC START OF A CYCLE

This service enables to start the selected program at a certain moment, event. to repeat it every day or week. There shall be the sufficient supply of water in the sterilizer, see par. 8.1.5. Load the material to be sterilized and close the door of the sterilization chamber. After the activation "Automatic start" the program menu and time selection function are shown. Select the program with arrows and confirm it first and then select the time selection function with arrows and confirm it again. Enter the time of the program start in the same way as described in par. 8.6.3. Select the way of repeating the program through the field with the variable text "Once", "Once a week" and "Daily". By means of the field "Back" enter the menu "Automatic cycle start" and by touching "Switch off" switch off the sterilizer – then the clock is shown on the display.

The program **P10 Vacuum test** can be selected in combination with any sterilization cycle, then the vacuum test comes first and the sterilization cycle is started if the vacuum test has been successful.

After the end of the operating cycle the jacket heating and the display illumination are switched off after 1 hour if the function "Uninterrupted preheating" is not activated" (par. 8.6.12).

8.6.11 AUTOMATIC DOOR OPENING

After the activation by touching the field "Confirm" "Automatic door opening" the door lock is released automatically after the end of the program. By means of the field "Confirm" also the reverse function is carried out, i.e. door opening is forbidden.

8.6.12 UNINTERRUPTED PREHEATING

After the activation by touching the field "Confirm" "Uninterrupted preheating" the sterilizer is being preheated for an unlimited time if the sterilizer is in the operating mode. In case this function is not activated, the sterilizer will be preheated for 1 hour, then it gets in the stand-by mode automatically. Return to the operating mode by touching the display.

8.6.13 AUTOMATIC WATERING

After the activation by touching the field "Confirm" "Automatic watering" an automatic process is started that secures a perfect watering of steam generator pump. There shall be no material to be sterilized placed in the sterilization chamber and the sterilization chamber door shall be closed. This process shall be performed when putting the sterilizer into operation with the internal tank of supply water being filled.

8.6.14 AUTOMATIC DEWATERING

After the activation by touching the field "Confirm" "Automatic dewatering" an automatic process is started that secures the water discharge from the steam generator and the piping. Before starting this process the inner supply water tank shall be discharged completely by means of the discharge hose and the connector 12. There shall be no

material to be sterilized placed inside the chamber and the sterilization chamber door shall be closed.

There shall be no material to be sterilized placed in the sterilization chamber and the sterilization chamber door shall be closed.

This procedure is recommended in case of a long-term putting the sterilizer out of operation or before transporting it. In case of danger of exposing the sterilizer to an ambient temperature lower than 0 °C also the water from the steam generator shall be discharged by an *authorized person*.

8.6.15 CHANGE OF PROGRAM PARAMETERS

Is not active with this sterilizer.

8.6.16 RECORDING A PROGRAM TO A CHIP CARD

After the activation by touching "Confirm" "Recording program to card" select the program to be recorded to a chip card by means of arrows. Then insert the chip card into the chip card reader opening **19** with the chip turned down and confirm by touching "Confirm". If the process of data transfer from the sterilizer to the chip card is OK, a simple acoustic signal is heard after ca. 6 sec. If the data transfer is not OK (e.g. because of inserting the chip card not properly), a varying acoustic signal is heard. After finishing the data transfer remove the card from the opening. By touching the field "Back" you get to the menu "General service settings".

8.6.17 RESTORING A PROGRAM FROM A CHIP CARD

After the activation by touching "Confirm" "Restoring program from card" select one of the program positions P01 to P10 you wish to record the new program to. Then insert the chip card into the chip card reader opening **19** with the chip turned down and confirm by touching "Confirm". If the process of data transfer from the chip card to the sterilizer is OK, a simple acoustic signal is heard after ca. 2 sec. If the data transfer from the chip card to the sterilizer is not OK (e.g. because of inserting the chip card not properly), a varying acoustic signal is heard. After finishing the data transfer remove the card from the opening. Then mark the last line "P11 Store settings" by means of the arrows and confirm by touching "Confirm". After switching on the illumination of the display **15** touch the field "Back" and get to the menu "General service settings".

8.6.18 AIR DETECTOR

Used for the air detector setting if the sterilizer is equipped with it (see Appendix A to the Instructions). If the air detector is activated, air presence in the sterilization chamber will be detected during the fractional pre-vacuum phase before the sterilization exposure. If the permitted quantity of air is exceeded, the sterilizer will show an error message.

8.6.19 SOUND-OFF MODE

It will switch off all acoustic signals.

8.7 INFORMATION

The display of information can be activated by touching the field "Info" on the touch-display **15**.

8.7.1 NUMBER OF CYCLES

Shows the number of all started cycles.

8.7.2 JACKET TEMPERATURE

Shows the temperature of the sterilization chamber heating jacket in °C.

8.7.3 CHAMBER TEMPERATURE

Shows the temperature in the sterilization chamber in °C. 2 or 4 values are displayed, if the program with the flexible sensor is selected. The upper ones are Mst temperatures – check and the lower ones are Slv temperatures – regulation. The temperatures of the fix sensor are on the left, on the right there are the temperatures of the flexible sensor, provided the respective program is selected.

8.7.4 CHAMBER PRESSURE

Shows the absolute pressure in the sterilization chamber in kPa. It shows the absolute pressure (kPa) in the sterilization chamber. Two values are displayed. The upper one is the Mst checking pressure; the lower one is Slv control pressure.

8.7.5 STEAM GENERATOR WATER LEVEL

If there is water enough in the steam generator, „OK“ is indicated, otherwise „Refill“.

8.7.6 STEAM GENERATOR PRESSURE

If „No pressure“ is indicated, there is not the full pressure in the steam generator. If „Under pressure“ is indicated, there is the full pressure in the steam generator.

8.7.7 SUPPLY TANK

If there is water enough in the supply tank, „OK“ is indicated, otherwise „Refill“.

8.7.8 DRAIN TANK

If it is not necessary to discharge the drain water, „OK“ is indicated, otherwise „Full“.

8.7.9 BATTERY

The spare battery voltage is displayed. The minimum voltage, at which the warning report starts to be shown, is 2.7 V. In this case have the battery exchanged by an *authorized person*. Otherwise in case of a fall out loss or disconnecting from mains the information on the last sterilizer condition, the user's setting and the charge counter can get lost, or, in case a sterilization cycle is running, this cycle can be broken.

8.7.10 SERIAL NUMBER

The serial number of the sterilizer is displayed.

8.7.11 SERVICE INSPECTION

Shows the date in YY-MM-DD format and the number of batches after which the next service inspection must be carried out.

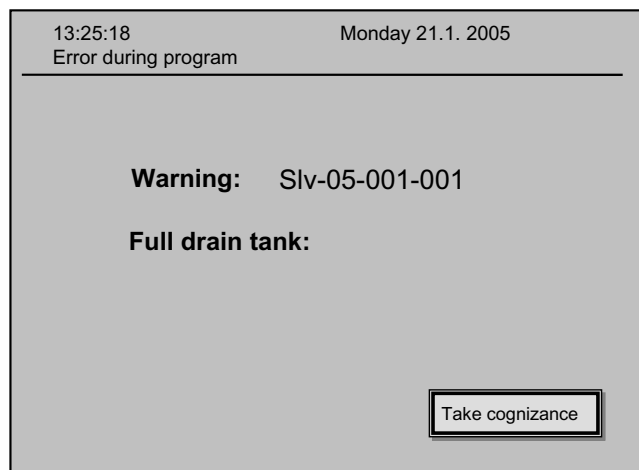
9 OPERATION FAILURES

The description of chapter 5.1 Indicating and operating elements is used in this chapter.

9.1 TECHNICAL SAFETY DEVICES

9.1.1 ERROR MESSAGES

In case of a failure the information on the failure condition and menu for approval of further operation of the sterilizer is shown on the display **15**, an acoustic signal is heard and the display shows:



The field "Acknowledge" must be activated by a touch. In case of an error message, number key for code entering is then offered.

After entering the right code and its approval by touching the field **15** the program is interrupted automatically.

The procedure is identical with the break of a running program by touching the field "Break" and subsequent entering the code.

In most cases the cause of the failure shall be repaired by an *authorized person*.

Caution :

In this case the load shall not be considered sterile.

9.2 ELECTRIC ENERGY OUTAGE

If a short-time outage of electric energy occurs during the sterilization cycle and no surpassing of the observed parameters takes place, the sterilization cycle continues automatically after the restoration of the electric power supply. The automatics tests the keeping of all observed parameters. In case of a longer outage of electric energy an error is reported after restoration of electric power supply.

Caution:

In case of a longer outage of electric energy, when the sterilization parameters are not kept, the load shall not be considered sterile.

10 MAINTENANCE, CLEANING AND ATTENDANCE

The description of chapter 5.1 Indicating and operating elements is used in this chapter.

10.1 CLEANING

Disconnect the unit from the source of electric energy before cleaning. Clean the unit only in cold state.

Following parts of the sterilizer are to be cleaned:

- Sterilization chamber **1**;
- Sterilization chamber drain screen **5**;
- Functional surface of the door plate **2**;
- External covers of the sterilizer;
- Touch display **15**;

10.1.1 CLEANING THE STERILIZATION CHAMBER

Use non-aggressive cleaning agents for chromium or stainless steel without abrasive additives that cannot cause a damage to the inner surface of the sterilization chamber (Ultrapur).

There is a drain screen **5** inserted in the drain neck in the bottom part of the chamber. Slide this screen carefully upwards, wipe the dirt around the neck with a cloth carefully, so that it does not get in the drain hole. Wash the screen with a water stream. After cleaning the chamber slide the screen in the drain neck hole up to the stop.

Clean once in two weeks.

10.1.2 CLEANING THE DOOR PLATE

For cleaning of the functional door plate **2** use non-aggressive cleaning agents for chromium or stainless steel without abrasive additives that cannot cause a damage to the surface of the door plate (Ultrapur).

Clean once in two weeks.

10.1.3 CLEANING THE COVERS AND THE DISPLAY

For cleaning of stainless covers round the door plate and the rear cover of the sterilizer use non-aggressive cleaning agents for chromium or stainless steel without abrasive additives, that cannot cause a damage to the surface of the covers (Ultrapur). Wash the side and the upper cover with wet cloth with detergent without abrasive additives. Clean the display with cleaning agents for monitor screens or TV screens. Do not use water! If water gets into the space behind the display there is a danger of functional damage to the electronic unit!

Clean once in two weeks.



Caution:

For cleaning of the sterilizer please do not use any aggressive agents. For any maintenance or cleaning the sterilizer shall be disconnected from mains!

10.2 SERVICE INSPECTIONS AND MAINTENANCE

For the reason of long service life and high operational reliability of the sterilizer we recommend to follow all cleaning and maintenance instructions.

It is necessary to carry out repeated inspections and to secure the operation ability of all safety devices. The operator must provide for checking of the steam sterilizer by an authorized person once in a year due to operational safety, functional reliability and economic efficiency. The keeper receives a written report with the inspection results.



Caution:

The sterilizer is provided with parts that, after disconnecting from mains, set themselves into the position that makes the measurement of the isolation resistance of the whole device impossible.



Caution:

The sterilizer contains parts that could be damaged or destroyed when applying the direct-current voltage of 500 V.

10.2.1 WATER QUALITY

There is distilled water or water treated by demineralization or reverse osmosis required for the purposes of steam generating for steam sterilization. Check the water quality every month.

Evaluation of the water quality see data in chapter 12.1

10.2.2 HALF-YEAR INSPECTION

Once in a half-year the operator performs following procedures:

- visual check of the door sealing **4**, in case of a mechanical damage replacing by a new one
- exchange of the aeration antibacterial filter **13**.

10.2.3 ANNUAL INSPECTION

For the reason of operational safety, functional reliability and economy have the sterilizer inspected by an *authorized person*. A trouble-free operation depends considerably on the state of all sensors, whose calibration shall be carried out every year.

During this inspection the automatic lock of the sterilization chamber is inspected from the viewpoint of the functional threads wear and of further fail-safe operation, all worn parts will be replaced by new ones, the lock function will be tested event. the lock adjusted.

The tightness of the tubing, state of hoses and screw joints shall be checked too.

Check of the safety valve

Follow the national regulations for the control and/or replacement of the safety valve **14**.

The manufacturer recommends the following procedure: Once a year, perform the inspection of the function of the sterilization chamber and the steam generator safety valve **14** that is accessible in the rear part of the sterilizer. The inspection may be carried out by an *authorized person* or a person with special training according to the appropriate national regulations.

To check the sterilization chamber and steam generator safety valve **14**, proceed as follows:

Switch the sterilizer in the operating mode (see Art. 8.1.2).

The steam generator will be pressurized within 10 minutes from the sterilizer switching on. After this time passes, disconnect the sterilizer from the mains by pulling the mains cord **18** out of the electric socket. Rotate the knob of the safety valve **14** counter clockwise (**protect your hand with a glove against burns**) until the valve spring is released.

If the safety valve is functional, steam must start to leak. Then rotate the knob to the initial position to close the valve.

Be extremely careful when performing this test! The steam starts to leak suddenly and fiercely.

When checking the steam generator safety valve **17** proceed in the same way with the difference that you need not start the sterilization cycle, the steam generator is pressurized within 10 minutes after switching the sterilizer on.

Revision of electric components

- Inspection of the wiring, especially the lead, connecting terminals and protective terminals. The integrity of the leads insulation (worn through, burnt out insulation etc.) and non-detachable connection of the leads in the terminals shall be checked.
- The resistance of the protective connection $R < 0.1 \text{ Ohm}$. The lead resistance is not taken into account.



Caution:

After the lapse of one year or after the seven hundredth cycle since the last inspection the unit shows the warning "Service inspection" after the switching-on.

10.2.4 BATTERY EXCHANGE

The sterilizer is provided with a spare battery CR 2430 that shall be exchanged once in two years. The exchange will be carried out by an *authorized person* during the annual inspections. See par. 8.7.9.



Caution:

If the mains cord **18** is disconnected from energy supply, the durability of the spare battery becomes shorter.

10.3 REPAIRS

In case of occurrence of some failures or damage to the electric device, the pressure vessel or connected safety devices, the steam sterilizer shall be put out of operation immediately and this fact shall be reported to the head of the appropriate department or service.

For the repairs only original or by manufacturer approved spare parts may be used.

Hoses and their screw joints shall be taken only from the sterilizer manufacturer as spare parts and their mounting shall be carried out only by an authorized person. The repairs and maintenance of the electric devices, pressure vessel or connected safety devices shall be carried out only by an *authorized person*.

Check of the sterilization efficiency

The sterilization efficiency is checked by means of biological tests that shall be performed in intervals that are determined by the standard EN 554 Medical means sterilization - Validation and continuous check of sterilization with wet heat as an obligatory technical standard for sterilization processes (valid for other countries another corresponding national regulation is valid).

For quicker and more often verification of sterilization efficiency we recommend to perform the Bowie & Dick test and Helix test (par. 4.4.2.3 and 4.4.2.4). Be aware that these tests do not replace the obligatory microbiological tests of sterilization efficiency!

The sterilization efficiency is affected by the chamber tightness considerably. Therefore we recommend to perform the Vacuum test before the appropriate sterilization program (par. 6.10).

10.4 REPORT INTO AN OPERATING BOOK OF A SANITARY INSTRUMENT

The authorized person makes a record into an operating book of a sanitary instrument:

- After installing the apparatus to the extent specified by the operating book of the sanitary instrument
- In the six month and annual inspections
- In case of changes in the apparatus
- In case of defects of the sterilizer.

11 ADDITIONAL MATERIAL AND CONSUMABLE ITEMS

The material can be ordered by means of the listed order codes.

11.1 MATERIAL SUPPLIED WITH THE DEVICE (STANDARD)

Material	Designation			Number of pieces
	STERIDENT	STERIMAT	STERIMAT Plus	
Sterilization chamber built-in piece	0338074	0338077	0338076	1
Perforated dish L* × 190 × 15	V316700	V316702		4
Perforated dish 440 × 216 × 15			V028420	4

Unloading holder	S467465	S467465	S467465	1
Discharge hose	S461322	S4613232	S461322	1
Pumping hose	S461323	S461323	S461323	1

*STERIDENT: L = 310 mm; *STERIMAT: L = 430 mm;

11.2 ADDITIONAL MATERIAL (ADITIVE)

Additional material	Designation			Number of pieces
	STERIDENT	STERIMAT	STERIMAT Plus	
Sieve **	S312770			1
Holder of wrapped material **	S312771			1
Container stainless steel 58 × 190 × 310**	0270072			2
Container stainless steel 71 × 190 × 310**	0270073			2
Container Al 136 × 188,5 × 298**	0270071			1
Flexible sensor			S462837	1
Thermoprinter DPT-6333-V.24-WOPS		0338415		1
Source DSV-6333		0338417		1
Cable DKA-278		0338416		1
Thermopaper DPA-048-TR1		0721129		
Antibacterial filter		0755101		2 pc/year
Bowie-Dick test pack		E7001030		1 pc/day
Steam chem. Integrator ProChem Steam		E7001020		
Biological indicator Prospore 2 Steam		E7001008		

**Sterilization chamber equipment.

11.3 USE OF THE STERILIZATION CHAMBER SPACE

The optimum layout of the goods in the sterilization chamber is enabled by rearranging and inserting of dishes of various sizes (4 pcs in the standard equipment).

Possible combinations of filling the sterilization chamber:

- Standard equipment: Built-in piece (1 piece) + dish (4 pieces);
- By giving a quarter turn of the built-in piece, the containers can be put in;
- Built-in piece (1 piece) + suitable containers;
- The containers are inserted directly in the sterilization chamber;

12 REQUIREMENTS ON OPERATING MEDIA

12.1 SUPPLY WATER

There is a distilled water (or fully demineralized water or water treated by reverse osmosis) required for the steam generating.

Recommendation:

We recommend using only of the distilled water because it usually contains a lower amount of non-condensable gases than the treated water usually does.

Recommended values for supply water are given below:

Additives	Condensate (steam)	Supply water (steam generator)
Residues after evaporation	≤ 1,0 mg/kg	≤ 10 mg/l
Silicium SiO ₂	≤ 0,1 mg/kg	≤ 1 mg/l
Ferrum	≤ 0,1 mg/kg	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/kg	≤ 0,005 mg/l
Plumbum	≤ 0,05 mg/kg	≤ 0,05 mg/l
Heavy metals besides ferrum, cadmium, plumbum	≤ 0,1 mg/kg	≤ 0,1 mg/l
Chlorides	≤ 0,1 mg/kg	≤ 2 mg/l
Phosphates	≤ 0,1 mg/kg	≤ 0,5 mg/l
Specific conductivity at 20 °C	≤ 3 µS/cm	≤ 15 µS/cm
PH value	5 - 7	5 - 7
Colour	colourless clear without sludges	colourless clear without sludges
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l

Caution:

Using the supply water with worse parameters than those described in this manual can reduce the service life of the unit or limit the parameters guaranteed by the manufacturer. It can cause a canceling of warranty by manufacturer.

Recommendation:

We recommend to keep the mains cord connected to the mains, even if the sterilizer is not running, otherwise the spare battery is being discharged and its durability becomes shorter.

12.2 ELECTRIC CONNECTION

The sterilizer requires power supply only. Before the sterilizer is connected, electric connection must be checked. The connection shall have the nominal voltage of 230 V, a protective wire and be dimensioned for 16 A. Connecting of the sterilizer to the mains is performed by plugging the mains cord plug 18 in the mains socket.

CAUTION:

The power supply cable plug must be within the reach of the sterilizer user for a need of disconnection from the power mains.

Recommendation:

We recommend to keep the mains cord connected to the mains, even if the sterilizer is not running, otherwise the spare battery is being discharged and its durability becomes shorter.

13 TRANSPORT AND STORAGE

13.1 TRANSPORT

- Discharge the sterilizer filling – waste water – according to Article 8.1.6 and the distilled water by means of the discharge hose and connector for the distilled water discharge 12.
- Switch on the automatic dewatering according to Article 8.6.14. Water from the inner sterilizer interconnection will be drawn to the waste vessel.
- Discharge the rest of the water from the waste vessel according to Article 8.1.6.
- Disconnect the sterilizer from mains.
- The sterilizer is transported in vertical position by catching it by the bottom edges.

Caution:

Do not carry the sterilizer by the bottom edge of the plastic cover! The sterilizer may be transported only with empty supply tanks!

- Transport the sterilizer in the original package.

13.2 STORAGE

Before the storage an *authorized person* discharges the supply tanks and the piping of the sterilizer. The sterilizer shall be put in its original package. The storage temperature shall not drop below 4 °C.

14 LIQUIDATION

14.1 PACKAGE

The package is made of wood, cardboard, paper and plastics.

Wood - hand over to incinerating plant;
Paper - hand over to recycling;
Plastics - hand over to liquidation.

14.2 STERILIZER

The unit consists of 80 % steel, 5 % electric material, 10 % plastics and 5 % other materials. An ecological liquidation of the disassembled unit shall be carried out by an *authorized person*.

In case of a sterilizer liquidation, the following items must be disassembled preferentially:

- Battery;
- Printed circuits;
- Visual display unit;
- Cable.



Caution:

For member states of the European Union:

- A. Product, which the user stops using and which becomes for the user a useless and which is



marked with a label .

The user shuts down it and notifies, in case of the Czech Republic, the manufacturer, in case of other member states of EU, the dealer.

The mentioned product is not possible to be disposed to municipal refuse and it is a subject to a mode in accordance with local regulations on disposal of electric and electronic equipment, which conform to WEEE (Waste Electric and Electronic Equipment) Directive as amended.

The dealer (in the Czech Republic it is the manufacturer) ensures necessary acts in accordance with the requirements of the local valid legislation in the field of waste (in the Czech Republic the law on waste No. 185/2001 Coll., as amended, and in accordance in the purchase agreement).

- B. Technical requirements for storage and treatment of electric waste, which is performed by the processor of the product or of its part as the electric waste:
- Place for collection and storage of electric waste is equipped with:
Hard surface, which is impermeable against the leakage of dangerous substances, cleaning aids, substances for absorption of leaked operating liquids, collecting means for incurred waste, device for dislocation of electric waste, in an appropriate way in terms of health and safety protection at work.
 - Place for treatment of electric waste is equipped with:
Appropriate equipment for determining the weight of the treated electric waste, hard surface, which is impermeable against the leakage of dangerous substances, appropriate containers for storage of incurred waste, appropriate storage space for disassembled construction units and parts

Treatment of electric waste:

To group the removed and disassembled parts of the electric waste in accordance with the requirements:

- of the local valid legislation in the field of waste.
- Position of the subject parts in the respective products are described in the Direction for use of the product.
- To apply only the technologies destined for treatment of electric waste, which ensure that it does not happen to a leakage of substances endangering the environment.

Preferentially demount from the waste:

From among the wastes, the following items must be disassembled preferentially:


- Batteries and accumulators;
- Printed circuits larger than 10 cm²;
- All other liquids – especially oils;
- Discharge lamps and fluorescent lamps – if the form a part of lighting;
- Liquid crystal displays larger than 100 cm²;
- Outer electric cables.

Parts, components and materials preferentially demounted from the electric waste according to the description to use or dispose in accordance with special legal regulations:

- local valid legislation in the field of waste.

For the countries outside of the European Union:



The mentioned-above described symbol  For proper disposal of electric and electronic equipment, please, ask for detailed information at your authorities or at the dealer of the device.

15 REGULATIONS AND STANDARDS

From the viewpoint of requirements on design and manufacturing of electrical appliances and pressure vessels this sterilizer fulfills all legal regulations, harmonized standards and recognized rules (see EU Conformity declaration that is an inseparable part of the documentation supplied along with each device) and is provided with all necessary safety, check and operation mechanisms.

16 GUARANTEED, SERVICE AND OPERATING LIFE OF THE DEVICE

The guarantee period is indicated in the Certificate of Guarantee. The guarantee shall apply to the defects of material or workmanship under the conditions that:

- The product was installed and used in accordance with the Operating Instructions;
- The defect was not caused by incorrect maintenance, unqualified intervention into the device, or damage by external influences.

The guarantee shall not be applied to the natural wear and tear of the material and to the consumables, e.g. the door seal, materials for recording equipment, accumulators, etc.).

If a defect occurs, claim your right for a guarantee repair at the nearest service centre of MMM. Specify the name and type of the device, its production number and manifestation of the defect (error message, printer output). If you meet the guarantee conditions, the service centre will, in its discretion, either repair the device or replace the defective part free of charge. MMM guarantees that all technical documents and spare parts will be available for the period of 10 years from the introduction of the device to the market and a safe and functional operation of the device will thus be ensured for the said period.

After termination of the said period, MMM will be able to ensure a safe and functional operation of the device only upon a further contractual agreement.

In accordance with the EU Directive no. 85/374/EEC (the law no. 59/1998 Sb. in the Czech Republic), MMM shall be responsible for any potential damage caused by a defect of the device for the period of 10 years from the introduction of the device to the market.

17 SUPPLEMENT

17.1 LIST OF ERROR MESSAGES

17.1.1 WARNING MESSAGES

Warning: Mst – 11 – XXX* – XXX*

Low battery

Cause	Removal by	Action to perform
Spare battery discharged	Service	Battery exchange

Warning: Mst – 13 – XXX* – XXX*

Printer not respond

Cause	Removal by	Action to perform
Printer not connected	Operator	Connect the printer and set in on-line state or cancel the protocol printing

Warning: Mst – 19 – XXX* – XXX*

Faulty process

Cause	Removal by	Action to perform
The lately started process is unsatisfactory	Operator	New cycle to be performed

Warning: Mst – 20 – XXX* – XXX*

Service inspection

Cause	Removal by	Action to perform
One year or 700 cycles since the last service inspection	Service	Sterilizer inspection

Warning: Slv – 01 – XXX* – XXX*

Door error

Cause	Removal by	Action to perform
Specified underpressure cannot be achieved	Service	Check the switch B17, valves, piping, the cooler
Door cannot be closed.	Service	Check the limit switches and door drive
Door cannot be opened.	Service	Check the limit switches and door drive

Warning: Slv – 03 – XXX* – XXX*

Error watering

Cause	Removal by	Action to perform
Max. water level in the inner tank not achieved	Operator	Continue the operation, prepare 7 l of distilled water for further refilling
Water cannot be refilled	Service	Check the pump, piping

Warning: Slv – 04 – XXX* – XXX*

Low water level

Cause	Removal by	Action to perform
Water level in the inner tank below the min. level	Operator	Refill the supply water according to par. 8.1.5

Warning: Slv – 05 – XXX* – XXX*

Full drain tank

Cause	Removal by	Action to perform
Drain tank is full	Operator	Discharge the used water according to par. 8.1.6

17.1.2 FAILURE MESSAGES

Error: Mst – 01 – XXX* – XXX*

Unexpected step

Cause	Removal by	Action to perform
Automatics error	Operator	Start the cycle again
Non-standard course of sterilization cycle phase	Service	Check the process

Error: Mst – 02 – XXX* – XXX*

Too short phase

Cause	Removal by	Action to perform
Automatics error	Operator	Start the cycle again
Non-standard course of sterilization cycle phase	Service	Check the process

Chyba: Mst – 03 – XXX* – XXX*

Příliš dlouhá fáze

Cause	Removal by	Action to perform
Automatics error	Operator	Start the cycle again
Non-standard course of sterilization cycle phase	Service	Check the process
Valve, heating or vacuum pump fault	Service	Check the valves, heating and vacuum pump

Error: Mst – 04 – XXX* – XXX*

Low temperature

Cause	Removal by	Action to perform
Untightness	Operator	Perform the vacuum test Start the cycle again
Air in the chamber	Service	Remove the untightness
Incorrect setting of sterilization cycle parameters.	Service	Check the parameters
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 05 – XXX* – XXX*

High temperature

Cause	Removal by	Action to perform
Untightness of the valve Y07	Service	Check, replace the valve
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 06 – XXX* – XXX*

Power cut

Cause	Removal by	Action to perform
Fall-out of power supply during the operation	Operator	Start the cycle again

Error: Mst – 07 – XXX* – XXX*

PT12 Disconnected

Cause	Removal by	Action to perform
Disconnected wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 08 – XXX* – XXX*
PT12 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 09 – XXX* – XXX*
PE12 Disconnected

Cause	Removal by	Action to perform
Disconnected wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 10 – XXX* – XXX*
PE12 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 12 – XXX* – XXX*
Slv – no response

Cause	Removal by	Action to perform
Automatics error	Operator	Wait for 10 s, start the cycle

Error: Mst – 14 – XXX* – XXX*
PT32 Disconnected

Cause	Removal by	Action to perform
Interrupted supply lead of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 15 – XXX* – XXX*
PT32 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Mst – 16 – XXX* – XXX*
IIC communication error

Cause	Removal by	Action to perform
Communication error	Service	Check;
Chip card inserted not properly	Operator	See par. 8.6.16 and 8.6.17
Wrong chip card	Operator	See par. 8.6.16 and 8.6.17

Error: Mst – 17 – XXX* – XXX*
Faulty calibrations

Cause	Removal by	Action to perform
The program cannot be started because of a faulty calibration	Service	Sterilizer calibration

Error: Mst – 18 – XXX* – XXX*
Faulty program

Cause	Removal by	Action to perform
The program cannot be started because a faulty program has been selected	Operator	Select the program
The program cannot be started because a faulty program has been selected	Service	Program download

Error: Slv – 02 – XXX* – XXX*
Door unblocked

Cause	Removal by	Action to perform
The safety device registered improper closing of the door	Service	Adjust the door switches.

Error: Slv – 06 – XXX* – XXX*
Generator interrupted

Cause	Removal by	Action to perform
Pump fault	Service	Check the pump

Error: Slv – 07 – XXX* – XXX*
Vacuum pump blocked

Cause	Removal by	Action to perform
El. vacuum pump protection registered the current rise above the max. limit	Service	Check, calibration

Error: Slv – 08 – XXX* – XXX*
Low temperature

Cause	Removal by	Action to perform
Leakage	Operator	Perform the vacuum test Restart the cycle
Incorrect setting of sterilization cycle parameters.	Service	Check the parameters
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 09 – XXX* – XXX*
High temperature

Cause	Removal by	Action to perform
Untightness of the valve Y07	Service	Check, exchange the valve
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 10 – XXX* – XXX*
PT11 Disconnected

Cause	Removal by	Action to perform
Disconnected wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Chyba: Slv – 11 – XXX* – XXX*
PT11 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 12 – XXX* – XXX*
PT31 Disconnected

Cause	Removal by	Action to perform
Disconnected wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 13 – XXX* – XXX*

PT31 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 14 – XXX* – XXX*

PE11 Disconnected

Cause	Removal by	Action to perform
Disconnected wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration.

Error: Slv – 15 – XXX* – XXX*

PE11 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 16 – XXX* – XXX*

PT21 Disconnected

Cause	Removal by	Action to perform
Disconnected wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 17 – XXX* – XXX*

PT21 Short-circuit

Cause	Removal by	Action to perform
Short-circuited wire of the temperature sensor	Service	Check, replace the sensor
Inaccurate setting of pressure and temperature sensors	Service	Check, calibration

Error: Slv – 18 – XXX* – XXX*

Error 24V

Cause	Removal by	Action to perform
24V not connected	Service	Check the power supply board

Error: Slv – 22 – XXX* – XXX*

High conductivity

Cause	Removal by	Action to perform
The cartridge in the water-treatment equipment is exhausted	Operator	Replace the cartridge for a fresh one
The water-treatment equipment is not connected to the power supply	Operator	Connect the equipment to the power supply
The water-treatment equipment is not connected to the water source	Operator	Open the drinking water intake

* a three-digit-number providing the *authorized person* with the information about the cycle phase, during which the error occurs;

17.2 EXAMPLES OF PRINTED DOCUMENTS

Protocol

Protocol + graphical record

STERIMAT+
030923

Set Program:
Unrapped instruments 134
Start:
13:01 27.01.2004

Evacuation 1:
Pmin = 12.7 kPa
Pmax = 12.7 kPa

Evacuation 2:
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Evacuation 3:
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Start of sterilization:
T = 135.7 °C
P = 317.8 kPa
13:31 27.01.2004

End of sterilization:
00:07:00
Tmin = 135.7 °C
Tmax = 136.0 °C
Pmin = 318.0 kPa
Pmax = 319.9 kPa

End of drying:
T = 88.1 °C
P = 25.9 kPa

End:
14:11 27.01.2004

Charge:
000009

Sterile

STERIMAT+
030923

Set Program:
Unrapped instruments 134
Start:
13:01 27.01.2004

Evacuation 1:
Pmin = 12.7 kPa
Pmax = 12.7 kPa

Evacuation 2:
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Evacuation 3:
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Start of sterilization:
T = 135.7 °C
P = 317.8 kPa
13:31 27.01.2004

End of sterilization:
00:07:00
Tmin = 135.7 °C
Tmax = 136.0 °C
Pmin = 318.0 kPa
Pmax = 319.9 kPa

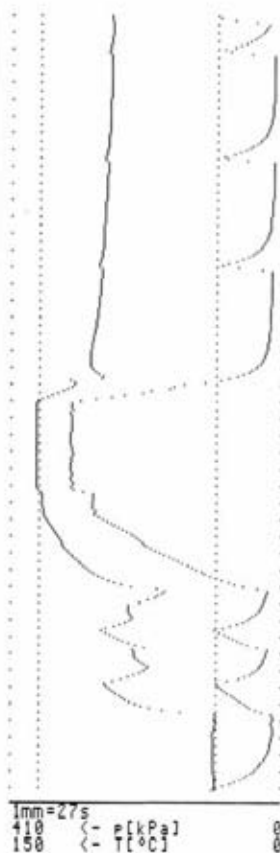
Start of drying:
T = 88.1 °C
P = 25.9 kPa

End of drying:
T = 88.1 °C
P = 25.9 kPa

End:
14:11 27.01.2004

Charge:
000009

Sterile



STERIMAT+
030923

Set Program:
Unwrapped instruments 134
Start:
13:01 27.01.2004

Evacuation 1:
Pmin = 12.7 kPa
Pmax = 12.7 kPa

Evacuation 2:
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Evacuation 3:
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Start of sterilization:
T = 131.7 °C
P = 20.0 kPa
13:31 27.01.2004

End of sterilization:
00:07:00
Tmin = 131.7 °C
Tmax = 131.7 °C
Pmin = 20.0 kPa
Pmax = 20.0 kPa

Start of drying:
P = 20.0 kPa
T = 131.7 °C

End of drying:
P = 20.0 kPa
T = 131.7 °C

End:
14:11 27.01.2004

Charge:
000009

Sterile

P	T
00:00:00	131.7
00:01:00	131.7
00:02:00	131.7
00:03:00	131.7
00:04:00	131.7
00:05:00	131.7
00:06:00	131.7
00:07:00	131.7
00:08:00	131.7
00:09:00	131.7
00:10:00	131.7
00:11:00	131.7
00:12:00	131.7
00:13:00	131.7
00:14:00	131.7
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P	T
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17.3 VALUES OF PROGRAM COURSES

Following table represents pressure and temperature at significant points and important time intervals of individual programs. For better orientation also the graphical program course is shown.

The pressure is in absolute values in kPa.

STERIDENT

| Significant points/ program | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 |
|---|--------|--------|--------|--------|---------|---------|----|---------|---------|--------|
| Start A | 100 | 100 | 100 | 100 | 100 | 100 | | 100 | 100 | 100 |
| 1. evacuation pressure B_{11} | 13 | 13 | 13 | 13 | 13 | 13 | | 13 | 13 | 13 |
| 1. evacuation delay $B_{11} - B_{12}$ | 0 min | 0 min | 0 min | 60 s | 0 s | 0 min | | 0 min | 0 s | 15 min |
| 1. steaming pressure C_{11} | * | 100 | 100 | 180 | 100 | 180 | | 100 | 180 | * |
| 1. steaming delay $C_{11} - C_{12}$ | * | 0 min | 0 min | 0 min | 0 min | 0 min | | 0 min | 0 min | * |
| 2. evacuation pressure B_{21} | * | 20 | 20 | 20 | 20 | 20 | | 20 | 20 | * |
| 2. evacuation delay $B_{21} - B_{22}$ | * | 0 min | 0 min | 60 s | 0 s | 0 min | | 0 min | 0 s | * |
| 2. steaming pressure C_{21} | * | 100 | 100 | 180 | * | 180 | | * | 180 | * |
| 2. steaming delay $C_{21} - C_{22}$ | * | 0 min | 0 min | 0 min | * | 0 min | | * | 0 min | * |
| 3. evacuation pressure B_{31} | * | 20 | 20 | 20 | * | 20 | | * | 20 | * |
| 3. evacuation delay $B_{31} - B_{32}$ | * | 0 min | 0 min | 60 s | * | 0 min | | * | 0 s | * |
| 3. steaming pressure C_{31} | * | * | * | 180 | * | 180 | | * | 180 | * |
| 3. steaming delay $C_{31} - C_{32}$ | * | * | * | 0 min | * | 0 min | | * | 0 min | * |
| 4. evacuation pressure B_{41} | * | * | * | 20 | * | 20 | | * | 20 | * |
| 4. evacuation delay $B_{41} - B_{42}$ | * | * | * | 60 s | * | 0 min | | * | 0 s | * |
| Equalizing pressure D_1 | 285 | 285 | 285 | 192 | 285 | 192 | | 285 | 285 | * |
| Equalizing delay $D_1 - D_2$ | 10 s | 100 s | 100 s | 120 s | 10 s | 10 s | | 10 s | 10 s | * |
| Exposure pressure E_1 | 310 | 310 | 310 | 210 | 310 | 210 | | 310 | 310 | * |
| Exposure temperature $E_1 - E_2$ | 134 °C | 134 °C | 134 °C | 121 °C | 134 °C | 121 °C | | 134 °C | 134 °C | * |
| Exposure time $E_1 - E_2$ | 4 min | 7 min | 7 min | 20 min | 7min | 20 min | | 3,5 min | 3,5 min | * |
| Drying pressure F_1 | 80 | 30 | 30 | 30 | 80 | 80 | | 40 | 40 | * |
| Evacuation delay at drying $F_1 - F_2$ | * | 4 min | 4 min | 4 min | 2,5 min | 2,5 min | | * | * | * |
| Aeration pressure at drying $G_1 - G_2$ | * | 90 | 90 | 90 | 90 | 90 | | * | * | * |
| Aeration delay at drying $G_1 - G_2$ | * | 0 min | 0 min | 0 min | 0 min | 0 min | | * | * | * |
| Drying time $F_1 - H$ | 0 min | 15 min | 25 min | 15 min | 6 min | 6 min | | 0 min | 0 min | * |
| Aeration pressure I | 100 | 100 | 100 | 100 | 100 | 100 | | 100 | 100 | 100 |

STERIMAT

| Significant points/ program | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 |
|---|--------|---------|---------|---------|--------|--------|----|---------|---------|--------|
| Start A | 100 | 100 | 100 | 100 | 100 | 100 | | 100 | 100 | 100 |
| 1. evacuation pressure B_{11} | 13 | 13 | 13 | 13 | 13 | 13 | | 13 | 13 | 13 |
| 1. evacuation delay $B_{11} - B_{12}$ | 0 min | 0 min | 0 min | 60 s | 0 s | 0 min | | 0 min | 0 s | 15 min |
| 1. steaming pressure C_{11} | * | 100 | 100 | 180 | 100 | 180 | | 100 | 180 | * |
| 1. steaming delay $C_{11} - C_{12}$ | * | 0 min | 0 min | 0 min | 0 min | 0 min | | 0 min | 0 min | * |
| 2. evacuation pressure B_{21} | * | 20 | 20 | 20 | 20 | 20 | | 20 | 20 | * |
| 2. evacuation delay $B_{21} - B_{22}$ | * | 0 min | 0 min | 60 s | 0 s | 0 min | | 0 min | 0 s | * |
| 2. steaming pressure C_{21} | * | 100 | 100 | 180 | * | 180 | | * | 180 | * |
| 2. steaming delay $C_{21} - C_{22}$ | * | 0 min | 0 min | 0 min | * | 0 min | | * | 0 min | * |
| 3. evacuation pressure B_{31} | * | 20 | 20 | 20 | * | 20 | | * | 20 | * |
| 3. evacuation delay $B_{31} - B_{32}$ | * | 0 min | 0 min | 60 s | * | 0 min | | * | 0 s | * |
| 3. steaming pressure C_{31} | * | * | * | 180 | * | 180 | | * | 180 | * |
| 3. steaming delay $C_{31} - C_{32}$ | * | * | * | 0 min | * | 0 min | | * | 0 min | * |
| 4. evacuation pressure B_{41} | * | * | * | 20 | * | 20 | | * | 20 | * |
| 4. evacuation delay $B_{41} - B_{42}$ | * | * | * | 60 s | * | 0 min | | * | 0 s | * |
| Equalizing pressure D_1 | 285 | 285 | 285 | 192 | 285 | 192 | | 285 | 285 | * |
| Equalizing delay $D_1 - D_2$ | 10 s | 100 s | 100 s | 120 s | 10 s | 10 s | | 10 s | 10 s | * |
| Exposure pressure E_1 | 310 | 310 | 310 | 210 | 310 | 210 | | 310 | 310 | * |
| Exposure temperature $E_1 - E_2$ | 134 °C | 134 °C | 134 °C | 121 °C | 134 °C | 121 °C | | 134 °C | 134 °C | * |
| Exposure time $E_1 - E_2$ | 4 min | 7 min | 7 min | 20 min | 7min | 20 min | | 3,5 min | 3,5 min | * |
| Drying pressure F_1 | 80 | 30 | 30 | 30 | 80 | 80 | | 40 | 40 | * |
| Evacuation delay at drying $F_1 - F_2$ | * | 5,5 min | 5,5 min | 5,5 min | 3 min | 3 min | | * | * | * |
| Aeration pressure at drying $G_1 - G_2$ | * | 90 | 90 | 90 | 90 | 90 | | * | * | * |
| Aeration delay at drying $G_1 - G_2$ | * | 0 min | 0 min | 0 min | 0 min | 0 min | | * | * | * |
| Drying time $F_1 - H$ | 0 min | 21 min | 37 min | 21 min | 8 min | 8 min | | 0 min | 0 min | * |
| Aeration pressure I | 100 | 100 | 100 | 100 | 100 | 100 | | 100 | 100 | 100 |

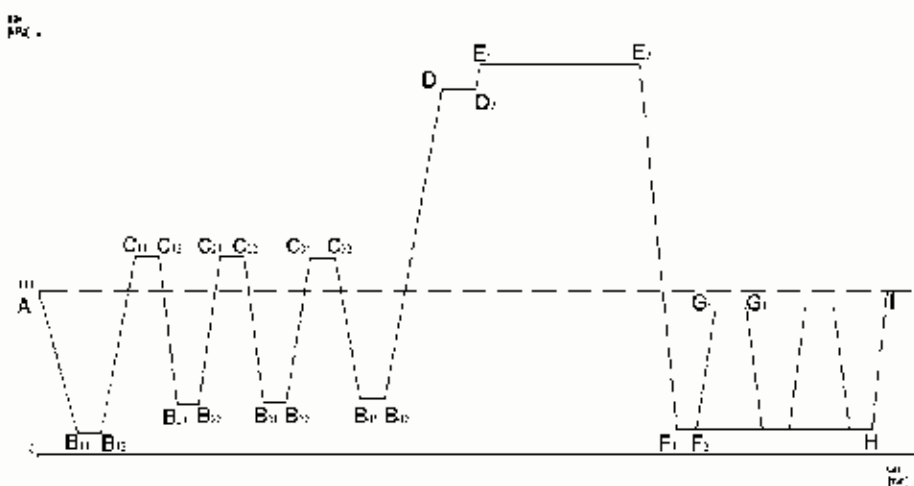
STERIMAT Plus

| Significant points/ program | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 |
|---|--------|--------|--------|--------|---------|---------|----|---------|---------|--------|
| Start A | 100 | 100 | 100 | 100 | 100 | 100 | | 100 | 100 | 100 |
| 1. evacuation pressure B_{11} | 13 | 13 | 13 | 13 | 13 | 13 | | 13 | 13 | 13 |
| 1. evacuation delay $B_{11} - B_{12}$ | 0 min | 0 min | 0 min | 60 s | 0 s | 0 min | | 0 min | 0 s | 15 min |
| 1. steaming pressure C_{11} | * | 100 | 100 | 180 | 100 | 180 | | 100 | 180 | * |
| 1. steaming delay $C_{11} - C_{12}$ | * | 0 min | 0 min | 0 min | 0 min | 0 min | | 0 min | 0 min | * |
| 2. evacuation pressure B_{21} | * | 20 | 20 | 20 | 20 | 20 | | 20 | 20 | * |
| 2. evacuation delay $B_{21} - B_{22}$ | * | 0 min | 0 min | 60 s | 0 s | 0 min | | 0 min | 0 s | * |
| 2. steaming pressure C_{21} | * | 100 | 100 | 180 | * | 180 | | * | 180 | * |
| 2. steaming delay $C_{21} - C_{22}$ | * | 0 min | 0 min | 0 min | * | 0 min | | * | 0 min | * |
| 3. evacuation pressure B_{31} | * | 20 | 20 | 20 | * | 20 | | * | 20 | * |
| 3. evacuation delay $B_{31} - B_{32}$ | * | 0 min | 0 min | 60 s | * | 0 min | | * | 0 s | * |
| 3. steaming pressure C_{31} | * | * | * | 180 | * | 180 | | * | 180 | * |
| 3. steaming delay $C_{31} - C_{32}$ | * | * | * | 0 min | * | 0 min | | * | 0 min | * |
| 4. evacuation pressure B_{41} | * | * | * | 20 | * | 20 | | * | 20 | * |
| 4. evacuation delay $B_{41} - B_{42}$ | * | * | * | 60 s | * | 0 min | | * | 0 s | * |
| Equalizing pressure D_1 | 285 | 285 | 285 | 192 | 285 | 192 | | 285 | 285 | * |
| Equalizing delay $D_1 - D_2$ | 10 s | 100 s | 100 s | 120 s | 10 s | 10 s | | 10 s | 10 s | * |
| Exposure pressure E_1 | 310 | 310 | 310 | 210 | 310 | 210 | | 310 | 310 | * |
| Exposure temperature $E_1 - E_2$ | 134 °C | 134 °C | 134 °C | 121 °C | 134 °C | 121 °C | | 134 °C | 134 °C | * |
| Exposure time $E_1 - E_2$ | 4 min | 7 min | 7 min | 20 min | 7 min | 20 min | | 3,5 min | 3,5 min | * |
| Drying pressure F_1 | 80 | 30 | 30 | 30 | 80 | 80 | | 40 | 40 | * |
| Evacuation delay at drying $F_1 - F_2$ | * | 7 min | 7 min | 7 min | 3,5 min | 3,5 min | | * | * | * |
| Aeration pressure at drying $G_1 - G_2$ | * | 90 | 90 | 90 | 90 | 90 | | * | * | * |
| Aeration delay at drying $G_1 - G_2$ | * | 0 min | 0 min | 0 min | 0 min | 0 min | | * | * | * |
| Drying time $F_1 - H$ | 0 min | 26 min | 46 min | 26 min | 10 min | 10 min | | 0 min | 0 min | * |
| Aeration pressure I | 100 | 100 | 100 | 100 | 100 | 100 | | 100 | 100 | 100 |

* Does not occur in this program.

P7 – Customer program, whose parameters are specified according to customer's requirements on program course.

Graph of the program course corresponding to the table of values



17.4 LIST OF TESTS FOR INDIVIDUAL PROGRAMS

The sterilizer is tested according to prEN 13060, which prescribes these tests for every program within the bounds of type tests performed by the manufacturer.

Table of tests

| Test / Program | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 |
|---|----|----|----|----|----|----|----|----|----|-----|
| Air-tightness at underpressure | + | + | + | + | + | + | | + | + | + |
| Dynamic changes of pressure | + | + | + | + | + | + | | + | + | + |
| Temperature profile of the empty chamber | + | + | + | + | + | + | | + | + | |
| Temperature profile with unwrapped massive load | + | | | | | | | | | |
| Temperature profile with double-wrapped massive load | | + | + | + | + | + | | | | |
| Temperature profile with double-wrapped porous small load | | + | + | + | + | + | | | | |
| Temperature profile with double-wrapped porous big load | | + | + | + | | | | | | |
| Temperature profile with the load of double-wrapped porous small articles | | + | + | + | | | | | | |
| Steam penetration into the porous load | | + | + | + | + | | | + | | |
| Steam penetration into the load with the cavity type A | | | | + | | + | | | + | |
| Drying of unwrapped massive load | | | | | | | | | | |
| Drying of double-wrapped massive load | | + | + | + | | | | | | |
| Drying of the load of double-wrapped porous small articles | | + | + | | | | | | | |
| Drying of porous big double-wrapped load | | + | + | + | | | | | | |

Designation of programs P1, P2 etc. see chapter 6.

+ Test performed;

17.5 TYPES OF STERILIZATION PROGRAMS

Types of sterilization cycles designed according to prEN 1360:

B – sterilization cycle for unwrapped or wrapped solid massive, porous and hollow material

S - sterilization cycle for material as specified by the manufacturer (of the sterilizer).

For the sterilizer the marked sterilization cycles are destined for porous material.

N - sterilization cycle for unwrapped solid massive material

Types of sterilization cycles are specified in the following table.

| Type of sterilization cycle/Program | P1 | P2 | P3 | P4 | P5 | P6 |
|-------------------------------------|----|----|----|----|----|----|
| B | | | | + | | + |
| S | | + | + | | + | |
| N | + | | | | | |

+ designation of the sterilization cycle type;

Brief operating instructions **STERIDENT, STERIMAT, STERIMAT Plus**



Initial state: **The sterilizer is connected to the el. energy source, it is in standby mode.**

1. Touch the touch-display of the sterilizer at any place.
2. Follow carefully the messages on the display and select the required function by touching with finger and confirm it by touching the field CONTINUE.
3. Perform the Vacuum test.
4. Perform the Bowie&Dick test (for porous material) or Helix test (for material with cavities).
5. Put the material to be sterilized in the chamber.
6. Turn the door ajar and press it for 4 seconds, it will be closed automatically.
7. Select the program by touching the field PROGRAM, mark the program by means of arrows and confirm it by touching the field CONTINUE.
8. Start the program by touching the field START THE PROGRAM.
9. After the signal of the program end open the door by touching the field OPEN THE DOOR
10. Unload the sterilized material.
11. By touching the field SWITCH OFF set the sterilizer to the standby mode.



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engineering

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